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INSTALLATION QUALIFICATION FOR HVAC SYSTEM

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 Lufter Sdn. Bhd.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		17-Oct-2022
Reviewed by: Ahmad Aslam	Assistant Manager		17-Oct-2022
Reviewed by: Koh Soon Yong	Project Manager		17-Oct-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: Quek Kiat Hoe	Deputy chief Pharmacist		11-Nov-2022
Reviewed by:		N/A	
Approved by: Steven	Manager		21 Nov 2022

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-SJMC02-HTL-VD-URS-R00	User Requirement Specification - New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.
2.	L-SJMC02-HTL-VD-DQ-R00	Design Qualification, New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	21 NOV 2022	Peng Peng	New

3.0 INTRODUCTION AND SCOPE

This document qualifies the new HVAC system installation for the New Hotlab within the Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan. Cleanrooms is to be in compliance with the principle of Current Good Manufacturing Practices (cGMP) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), ISO clean room guidelines, and World Health Organization (WHO) guidelines on GMP. 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".

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.



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5.0 ROLES & RESPONSIBILITY

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

Company	Job Title	Responsibility
Subang Jaya Medical Centre	Client Representative	To review the IQ protocol/report. To provide approval to the submitted IQ protocol/ report. To review vendor's specification against the approved quotation. To provide approval to the submitted documents. To ensure all relevant technical specifications in vendor's documents are correct. To verify and approve all results of the IQ report.
Lufter Sdn. Bhd.	Validation Executive Project Manager Project Engineer	To prepare the IQ protocol. To execute qualification according to approved protocol.



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6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	A/C	Acceptance Criteria
2.	AHRI	Air-Conditioning, Heating and Refrigeration Institute
3.	AHU	Air Handling Unit
4.	APB	Active Passbox
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.	B	Base
9.	BIBO	Bag in/Bag out
10.	Cert	Certificate
11.	cGMP	Current Good Manufacturing Practices
12.	C/W	Come With
13.	D	Depth
14.	DQ	Design Qualification
15.	DPG	Differential Pressure Gauge
16.	FPG	Filter Pressure Gauge
17.	GEP	Good Engineering Practices
18.	H	Height
19.	HFC	HEPA Filter Chamber
20.	HEPA	High-Efficiency Particulate Air
21.	HVAC	Heating, Ventilation and Air Conditioning
22.	IQ	Installation Qualification
23.	ISO	International Standardization for Organization
24.	L	Length
25.	NC	Not Controlled
26.	No	Number
27.	PDT	Pressure Differential Transmitter
28.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
29.	Ref	Reference
30.	SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
31.	UNCL	Unclassified
32.	T	Thickness
33.	TRH	Temperature & Humidity
34.	URS	User Requirement Specification
35.	W	Width
36.	WHO	World Health Organization

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7.0 SYSTEM DESCRIPTION

7.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed for the classified cleanroom consists of two (2) units of new AHU which are designed to supply condition air to the cleanroom of the New Hotlab as per Table 2 under Section 7.2.

The new AHU-1 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the air will be further cooled down at the chilled water post cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H14 HEPA filter at the HEPA filter terminal before being released into the rooms.

The new AHU-2 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the air will be further cooled down at the chilled water post-cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H13 HEPA filter at the HEPA Filter Chamber before being released into the rooms.

For AHU-1 and AHU-2, 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-1 and AHU-2 will then pass through the BIBO filtration system and exhaust fan system before being exhausted out to atmosphere from the chimney.



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AHU	Rooms / Equipment where air will be exhausted out	BIBO Filtration System
AHU-1	PET/CT Hotlab	BIBO-1
	Biosafety Cabinet (PET/CT Hotlab)	BIBO-2A
	SPECT/CT Hotlab	BIBO-1
	Biosafety Cabinet (SPECT/CT Hotlab)	BIBO-2A
	Airlock 1	BIBO-1
	Clean Corridor	BIBO-1
	Gown Room	BIBO-1
	Component Preparation Room	BIBO-1
	Change Room 1	BIBO-1
	Active Passbox 1	BIBO-1
	Active Passbox 2	BIBO-1
	Active Passbox 3	BIBO-1
	Radioiodine	BIBO-1
AHU-2	Fume Hood (Radioiodine)	BIBO-3
	Change Room 2	BIBO-1
	QC Room	BIBO-1
	Transfer Room	BIBO-1

Table 1: Air Exhausted out from room/equipment

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7.2 Cleanrooms Operating Conditions

Table 1 below shows the cleanroom and active passbox parameters designed to meet the design parameters required for classified and non-classified area as stated in the URS document (L-SJMC02-HTL-VD-URS; under section 8.2).

AHU/ Exhaust Fan	Room Description	Room No.	Room ISO Classification	Pressure (Pa) (ref. atmosphere)	Relative Humidity (%)	Temperature (°C)	Air Change
AHU-1	PET/CT Hotlab	HL01	ISO 5	55	50 - 60	18 - 22	≥ 120
	SPECT/CT Hotlab	HL02	ISO 5	55	50 - 60	18 - 22	≥ 95
	Airlock 1	HL03	ISO 5	0	50 - 60	18 - 22	≥ 40
	Clean Corridor	HL04	ISO 5	40	50 - 60	18 - 22	≥ 40
	Gown Room	HL05	ISO 5	30	50 - 60	18 - 22	≥ 110
	Component Prep. Room	HL06	ISO 7	30	50 - 60	18 - 22	≥ 35
	Change Room 1	HL07	ISO 7	15	50 - 60	18 - 22	≥ 35
	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	≥ 60
	Change Room 2	HL09	ISO 8	20	50 - 60	18 - 22	≥ 45
	QC Room	HL10	UNCL	-5	NC	20 - 24	≥ 20
	Transfer Room	HL11	ISO 8	20	50 - 60	18 - 22	≥ 50
EF-4	Decay Area	HL12	NC	-5	NC	NC	≥ 10

Table 1: Cleanroom and Active Passbox Parameter

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8.0 SYSTEM BOUNDARIES

The airflow schematic diagram (**L-SJMC02-HTL-DC-HVAC-06, L-SJMC02-HTL-DC-HVAC-07, L-SJMC02-HTL-DC-HVAC-08**) illustrates the components which comprise the HVAC System and the airflow direction.

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

- Air Handling Unit (AHU) System
- High Efficiency Particulate Air (HEPA) Filter
- Ducting System
- Differential Pressure Transmitter for Room (PDT)
- Differential Pressure Gauge for AHU and BIBO (FPG)
- Temperature & Humidity Transmitter for Duct and Room (TRH)
- Electrical Air Heater
- Exhaust Fan
- BIBO Filtration System
- Control Panel

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	Design - Design Documentation Record (General)	IQ-01
2	Nameplate Verification	IQ-02
3	Documentation Verification - Calibration Verification Record	IQ-03
4	Documentation Verification - Filter Grade Certification	IQ-04
5	Installation Verification - Pre-Operational Check (Ducting System)	IQ-05
6	Installation Verification - HEPA Filter Installation	IQ-06
7	Installation Verification (System) - Installation Against Drawing	IQ-07
8	Installation Verification (System) - Electrical Control Panel	IQ-08
9	Support - Change Control Record	IQ-09

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10.0 TESTING RATIONALE

A/C Ref.	Acceptance Criteria (A/C)	Rationale
1	Approved system design documentation is available.	To provide documented evidence that all required design documentation(s) is available and has been approved by the relevant parties.
2	The data on equipment nameplates is consistent with the design specification.	To provide documented evidence that the data on all equipment nameplates conforms to the design specification.
3	A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.	To provide documented evidence that all critical instruments have been calibrated.
4	Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.	To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.
5	The installation of the ducting system complies with the specification of ductwork installation and all mechanical works are as per the latest layout drawing.	To provide documented evidence that all ducting has been installed according to the general specification of ductwork installation.
6	HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process.	To provide documented evidence that all HEPA filters have been installed correctly, in good condition and conforms to their target efficiency.
7	The installation of all mechanical work is as per the approved design layout.	To provide documented evidence that the mechanical work has been installed according to the approved design layout.
8	The construction of control panels and other electrical installations complies with the safety standard.	To provide documented evidence to proof the safety of the control panels and other electrical installations.
9	Records for all changes made to the system throughout the execution of this checking procedure are available and further tests required after the changes made have been conducted.	To provide documented records of all changes made to the system upon installation.



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Title: Design - Design Documentation Record (General)			Test No: IQ-01			
Objective: To provide documented evidence that all required design documentation(s) are available and has been approved by the relevant parties.						
Pre-requisites: All documents should be reviewed and approved.						
Method: Record details of the design documentation; include the document reference, title, version, and status and approval date.						
Acceptance Criteria: Approved system design documentation is available.						
Results:						
Document Type	Document Ref.	Document Title	Document Version	Document Status	Approval Date	Verified By (Initial & Date)
Validation	L-SJMC02-HTL-VD-0A	Design Qualification	00	Approved	24-Aug-2022	10-Feb-2023
Comments/Deviations/Supporting Documentation: NA 10-Feb-2023						
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):	Date:		13-Feb-2023	

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Title:	Nameplate Verification	Test No: IQ-02
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Objective:

To provide documented evidence that the data on all equipment nameplates conforms to the design specification.

Method:

Document the name, model, and other information found on the nameplate and compare against the design specification. Serial number shall be recorded in the test sheet as found at site. Other information not available on the name plate should be verified against the documents supplied by contractor. (Picture of the nameplate should be attach at the attachment section).

Acceptance Criteria:

The data on all equipment nameplates is consistent with the design specification.

Results:

Equipment Name	Description	Acceptance Criteria	As Found	Conformity (Yes/No)	Verified By (Initial & Date)
Air Handling Unit (AHU-1)	Model	A1(M)1138H-1290W	A1 (m) 1138H-1290W	Yes / No	HA 10-Feb-2023
	Serial Number	* Record at site	m 19317	Yes / No	HA 10-Feb-2023
	Manufacturer	Welcome Air-Tech (M) Sdn. Bhd.	Welcome Air - Tech (m) Sdn. Bhd.	Yes / No	HA 10-Feb-2023
	Total Supply Air Quantity, CFM	3,465	3,465	Yes / No	HA 10-Feb-2023
	External Static Pressure, Pa	625	625	Yes / No	HA 10-Feb-2023
	Fan Brand	Kruger	Kruger	Yes / No	HA 10-Feb-2023
	Fan Model	BNC-R400/DII(II)	BNC-R400 / DII (II)	Yes / No	HA 10-Feb-2023
	Fan Motor, KW	5.5	5.5	Yes / No	HA 10-Feb-2023
	Poles / Volts / Hz	2P/415/50	2P/415/50	Yes / No	HA 10-Feb-2023



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Title:		Nameplate Verification		Test No: IQ-02	
Equipment Name	Description	Acceptance Criteria	As Found	Conformity (Yes/No)	Verified By (Initial & Date)
Air Handling Unit (AHU-2)	Model	A1(M)0985H-1138W	A1 (m) 0985 H - 1138W	Yes / No	<i>HA</i> 10-Feb-2023
	Serial Number	* Record at site	m19318	Yes / No	<i>HA</i> 10-Feb-2023
	Manufacturer	Welcome Air-Tech (M) Sdn. Bhd.	Welcome Air-Tech (m) Sdn Bhd	Yes / No	<i>HA</i> 10-Feb-2023
	Total Supply Air Quantity, CFM	1,450	1,450	Yes / No	<i>HA</i> 10-Feb-2023
	External Static Pressure, Pa	875	875	Yes / No	<i>HA</i> 10-Feb-2023
	Fan Brand	Kruger	Kruger	Yes / No	<i>HA</i> 10-Feb-2023
	Fan Model	BNC-R315/DII(II)	BNC-R315 / 011(11)	Yes / No	<i>HA</i> 10-Feb-2023
	Fan Motor, KW	2.2	2.2	Yes / No	<i>HA</i> 10-Feb-2023
Poles / Volts / Hz		2P/415/50	2p / 415 / 50	Yes / No	<i>HA</i> 10-Feb-2023

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Title:		Nameplate Verification		Test No: IQ-02	
Equipment Name	Description	Acceptance Criteria	As Found	Conformity (Yes/No)	Verified By (Initial & Date)
Exhaust Fan (EF-1)	Model	BSB 355 DII	BSB 355 DII	Yes / No	HA 10-Feb-2023
	Serial Number	* Record at site	220849467-01 1000	Yes / No	HA 10-Feb-2023
	Static Pressure, Pa	1,000	1,000	Yes / No	HA 10-Feb-2023
	Fan Brand	Kruger	Kruger	Yes / No	HA 10-Feb-2023
	Fan Motor, KW	4.0	4.0	Yes / No	HA 10-Feb-2023
Exhaust Fan (EF-2A)	Volts / Poles / Hz	415/2/50	415/2/50	Yes / No	HA 10-Feb-2023
	Model	BSB 280 DI	BSB 280 DI	Yes / No	HA 10-Feb-2023
	Serial Number	* Record at site	220849467-02 0001	Yes / No	HA 10-Feb-2023
	Static Pressure, Pa	1000	1000	Yes / No	HA 10-Feb-2023
	Fan Brand	Kruger	Kruger	Yes / No	HA 10-Feb-2023
Exhaust Fan (EF-2B)	Fan Motor, KW	1.5	1.5	Yes / No	HA 10-Feb-2023
	Volts / Poles / Hz	415/2/50	415/2/50	Yes / No	HA 10-Feb-2023



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Nameplate Verification		Test No: IQ-02			
Equipment Name	Description	Acceptance Criteria	As Found	Conformity (Yes/No)	Verified By (Initial & Date)
Exhaust Fan (EF-3A)	Type	FQ 281 N4A	FQ 281 N4A	Yes/No	10-Feb-2023
	Serial Number	* Record at site	5042	Yes/No	10-Feb-2023
	Manufacturer	Ferrari	Ferrari	Yes/No	10-Feb-2023
	Static Pressure, Pa	1000	1000	Yes/No	10-Feb-2023
	Fan Brand	Ferrari	Ferrari	Yes/No	10-Feb-2023
	Fan Motor, KW	0.75	0.75	Yes/No	10-Feb-2023
Exhaust Fan (EF-4)	Volts / Poles / Hz	415/2/50	415/2/50	Yes/No	10-Feb-2023
	Type	FA 311 R4A	FA 311 R4A	Yes/No	10-Feb-2023
	Serial Number	* Record at site	5043	Yes/No	10-Feb-2023
	Manufacturer	Ferrari	Ferrari	Yes/No	10-Feb-2023
	Static Pressure, Pa	1,000	1,000	Yes/No	10-Feb-2023
	Fan Brand	Ferrari	Ferrari	Yes/No	10-Feb-2023
Exhaust Fan (EF-4)	Fan Motor, KW	0.37	0.37	Yes/No	10-Feb-2023
	Volts / Poles / Hz	415/2/50	415/2/50	Yes/No	10-Feb-2023

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Title:		Nameplate Verification			Test No: IQ-02	
Equipment Name	Description	Acceptance Criteria	As Found	Conformity (Yes/No)	Verified By (Initial & Date)	
HEPA Filter Chamber (HFC-2-01)	Model	X1(M)0833H-0985W	X1 (M) 0833 H - 0985 W	Yes/ No	HA 10-Feb-2023	
	Serial Number	* Record at site	M 19319	Yes/ No	HA 10-Feb-2023	
	Manufacturer	Welcome Air-Tech (M) Sdn. Bhd.	Welcome Air-Tech (M) Sdn. Bhd.	Yes/ No	HA 10-Feb-2023	
	Total Supply Air Quantity, CFM	1,450	1,450	Yes/ No	HA 10-Feb-2023	
Electrical Heater (EH-1-01)	Manufacturer	Welcome Air-Tech (M) Sdn. Bhd.	Welcome Air - Tech (M) Sdn. Bhd.	Yes/ No	HA 10-Feb-2023	
Electrical Heater (EH-2-01)	Manufacturer	Welcome Air-Tech (M) Sdn. Bhd.	Welcome Air - Tech (M) Sdn. Bhd.	Yes/ No	HA 10-Feb-2023	
BIBO-1	Manufacturer	Trox	Trox	Yes/ No	HA 10-Feb-2023	
	Dimension	710 X 553 X 710 mm	710 x 553 x 710 mm	Yes/ No	HA 10-Feb-2023	
BIBO-2A	Manufacturer	Trox	Trox	Yes/ No	HA 10-Feb-2023	
	Dimension	710 X 553 X 710 mm	710 x 553 x 710 mm	Yes/ No	HA 10-Feb-2023	
BIBO-3	Manufacturer	Trox	Trox	Yes/ No	HA 10-Feb-2023	
	Dimension	710 X 553 X 710 mm	710 x 553 x 710 mm	Yes/ No	HA 10-Feb-2023	
BIBO-4	Manufacturer	Trox	Trox	Yes/ No	HA 10-Feb-2023	
	Dimension	710 X 553 X 405 mm	710 x 553 x 405 mm	Yes/ No	HA 10-Feb-2023	

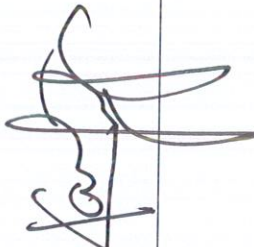


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Title:	Nameplate Verification	Test No: IQ-02
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Comments/Deviations/Supporting Documentation:
Refer to Attachments

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Feb-2023
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Title:	Documentation Verification – Calibration Verification Record (General)				
Objective:	To provide documented evidence that all critical instruments have been calibrated.				
Pre-requisites:	Device Assessment (Catalogues) should be provided at the attachment section.				
Method:	Review calibration certification available for each of the critical instruments; note the calibration certificate reference, calibration frequency and calibration due date.				
Acceptance Criteria:	A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.				

Test No: IQ-03



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Title: Documentation Verification – Calibration Verification Record (General) **Test No:** IQ-03

Results:

Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
TRH-1-04	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Duct Sensor	At Main Exhaust duct (AHU-1)	Yearly	13-Feb-2023	13-Feb-2024	PSM-23012309	AX 13-Feb-2023
TRH-2-04	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Duct Sensor	At Main Exhaust duct (AHU-2)	Yearly	13-Feb-2023	13-Feb-2024	PSM-23012310	AX 13-Feb-2023
TRH-R-01	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	PET/CT Hotlab	Yearly	13-Feb-2023	13-Feb-2024	PSM-23012302	AX 13-Feb-2023
TRH-R-02	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	SPECT/CT Hotlab	Yearly	13-Feb-2023	13-Feb-2024	PSM-23012300	AX 13-Feb-2023
TRH-R-03	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Airlock 1	Yearly	13-Feb-2023	13-Feb-2024	PSM-23012303	AX 13-Feb-2023



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Title: Documentation Verification – Calibration Verification Record (General)							Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)	
TRH-R-04	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Clean Corridor	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012301	[Signature] 13-Feb-2023	
TRH-R-05	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Gown Room	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012304	[Signature] 13-Feb-2023	
TRH-R-06	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Component Prep. Room	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012319	[Signature] 13-Feb-2023	
TRH-R-07	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Change Room 1	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012305	[Signature] 13-Feb-2023	
TRH-R-08	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Radioiodine	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012307	[Signature] 13-Feb-2023	

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Title: Documentation Verification – Calibration Verification Record (General)							Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)	
TRH-R-09	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Change Room 2	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012308	 13-Feb-2023	
TRH-R-11	Combine Duct Temperature & Humidity Transmitter Rotronic Model: HF3 Space Sensor	Transfer Room	Yearly	13-Feb-2023	13-Feb-2024	PSYN - 23012306	 13-Feb-2023	
FPG-2-03	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	HEPA Filter Chamber (HFC-2-01)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1220-23	 10-Feb-2023	
FPG-BIBO-S1	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	BIBO-1	Yearly	17-Jan-2023	17-Jan-2024	CTP 1228-23	 10-Feb-2023	
FPG-BIBO-S2	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	BIBO-1	Yearly	17-Jan-2023	17-Jan-2024	CTP 1221-23	 10-Feb-2023	

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Title: Documentation Verification – Calibration Verification Record (General)						Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
FPG-BIBO-2A	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	BIBO-2A	Yearly	17-Jan-2023	17-Jan-2024	CTP 1219-23.	<i>[Signature]</i> 10-Feb-2023
FPG-BIBO-3	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	BIBO-3	Yearly	17-Jan-2023	17-Jan-2024	CTP 1222-23	<i>[Signature]</i> 10-Feb-2023
FPG-BIBO-4	Dwyer Differential Pressure Transmitter 0-750 Pa Model: 2000-750PA	BIBO-4	Yearly	17-Jan-2023	17-Jan-2024	CTP 1223-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-01	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	PET/CT Hotlab / Clean Corridor	Yearly	19-Jan-2023	19-Jan-2024	CTP 1246-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-02	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	SPECT/CT Hotlab / Clean Corridor	Yearly	19-Jan-2023	19-Jan-2024	CTP 1242-23	<i>[Signature]</i> 10-Feb-2023



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Documentation Verification – Calibration Verification Record (General)						Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
PDT-R-03	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Gown Room / Airlock 1	Yearly	19-Jan-2023	19-Jan-2024	CTP 1244-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-04	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Airlock 1 / Clean Corridor	Yearly	19-Jan-2023	19-Jan-2024	CTP 1238-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-05	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Gown Room / Change Room 1	Yearly	19-Jan-2023	19-Jan-2024	CTP 1243-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-06	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Change Room 1 / Component Prep. Room	Yearly	19-Jan-2023	19-Jan-2024	CTP 1247-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-07	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Change Room 1 / Med Prep Area	Yearly	19-Jan-2023	19-Jan-2024	CTP 1250-23	<i>[Signature]</i> 10-Feb-2023



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Documentation Verification - Calibration Verification Record (General)						Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
PDT-R-08	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Transfer Room / Radioiodine	Yearly	19-Jan-2023	19-Jan-2024	CTP 1241-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-09	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Change Room 2 / Radioiodine	Yearly	19-Jan-2023	19-Jan-2024	CTP 1249-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-10	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Change Room 2 / Med Prep Area	Yearly	19-Jan-2023	19-Jan-2024	CTP 1245-23	<i>[Signature]</i> 10-Feb-2023
PDT-R-12	Dwyer Differential Pressure Transmitter 0-60 Pa Model: DM-053	Transfer Room / Med Prep Area	Yearly	19-Jan-2023	19-Jan-2024	CTP 1248-23	<i>[Signature]</i> 10-Feb-2023



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Title:	Documentation Verification – Calibration Verification Record (General)	Test No: IQ-03
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Comments/Deviations/Supporting Documentation:

Refer to Calibration Certificate (Hardware Documents)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13 - Feb - 2023
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Title:	Documentation Verification – Filter Grade Certification	Test No: IQ-04
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Objective/Purpose:

To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.

Pre-requisites:

System design reviews have been completed.

Method:

For each filter referenced below, ensure a fully valid filter efficiency certificate is available.

Acceptance Criteria:

Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.

Results:

AHU/BIBO	HEPA Filter ID Tag No.	Acceptance Criteria		As Found			Verified By (Initial & Date)
		Grade & Type	Grade & Type	Grade & Type	Serial No.	Cert. Ref.	
AHU-1	THF-01	JAF 1220 X 762 X 69 mm Grade H14	JAF 1220 x 762 x 69 mm Grade H14	J0589399	JVU2-AB4- 762122069-N22-P2	 10-Feb-2023	
	THF-02	JAF 1220 X 762 X 69 mm Grade H14	JAF 1220 x 762 x 69 mm Grade H14	J0589398	JVU2-AB4- 762122069-N22-P2	 10-Feb-2023	
	THF-03	JAF 305 X 610 X 69 mm Grade H14	JAF 305 x 610 x 69 mm Grade H14	J0589405	JVU2-AB4- 30561069-N22-P2	 10-Feb-2023	
	THF-04	JAF 1200 X 600 X 69 mm Grade H14	JAF 1200 x 600 x 69 mm Grade H14	J0589401	JVU2-AB4- 600120069-N22-P2	 10-Feb-2023	
	THF-05	JAF 1200 X 600 X 69 mm Grade H14	JAF 1200 x 600 x 69 mm Grade H14	J0589400	JVU2-AB4- 600120069-N22-P2	 10-Feb-2023	
	THF-06	JAF 610 X 610 X 69 mm Grade H14	JAF 610 x 610 x 69 mm Grade H14	J0589404	JVU2-AB4- 61061069-N22-P2	 10-Feb-2023	

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Documentation Verification – Filter Grade Certification						Test No: IQ-04	
AHU/BIBO	HEPA Filter ID Tag No.	Acceptance Criteria		As Found		Verified By (Initial & Date)	
		Grade & Type	Grade & Type	Serial No.	Cert. Ref.		
AHU-1	THF-07	JAF 610 X 610 X 69 mm Grade H14	JAF 610 X 610 X 69 mm Grade H14	J0589403	JVU2-AB4 - 61061069 - N22 - P2	<i>[Signature]</i>	10-Feb-2023
	THF-08	JAF 610 X 610 X 69 mm Grade H14	JAF 610 X 610 X 69 mm Grade H14	J0589402	JVU2-AB4 - 61061069 - N22 - P2	<i>[Signature]</i>	10-Feb-2023
AHU-2	HFC-2-01	JAF 610 X 610 X 292 mm Grade H13	JAF 610 X 610 X 292 mm Grade H13	J0550852	JVU1-6103HC - 610610292 - N2 - P3	<i>[Signature]</i>	10-Feb-2023
BIBO-1	HF-BIBO-1-S1	TROX 610 X 610 X 292 mm Grade H13	JAF 610 X 610 X 292 mm Grade H13	100958321 - 10001	DE 1614133 / 020	<i>[Signature]</i>	10-Feb-2023
	HF-BIBO-1-S2	TROX 610 X 610 X 292 mm Grade H13	TROX 610 X 610 X 292 mm Grade H13	100958321 - 10002	DE 1614133 / 020	<i>[Signature]</i>	10-Feb-2023
BIBO-2A	HF-BIBO-2A	TROX 610 X 610 X 292 mm Grade H13	TROX 610 X 610 X 292 mm Grade H13	100958321 - 10000	DE 1614133 / 020	<i>[Signature]</i>	10-Feb-2023
BIBO-3	HF-BIBO-3	TROX 610 X 610 X 292 mm Grade H14	TROX 610 X 610 X 292 mm Grade H14	100958321 - 20000	DE 1614133 / 030	<i>[Signature]</i>	10-Feb-2023
BIBO-4	HF-BIBO-4	TROX 305 X 610 X 292 mm Grade H13	TROX 305 X 610 X 292 mm Grade H13	100958321 - 00000	DE 1614133 / 010	<i>[Signature]</i>	10-Feb-2023

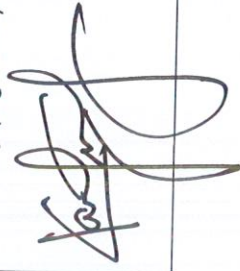


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Installation Qualification		Doc. No. Rev. No.	L-SJMC02-HTL-VD-IQ-HVAC-01 00	Effective Date Total Page(s)	21 NOV 2022 28 of 46
Title:	Documentation Verification – Filter Grade Certification				Test No: IQ-04
Comments/Deviations/Supporting Documentation: Refer to Filter Injection Report (Hardcopy Documents)					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 13-Feb-2023.	

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Title: Installation Verification - Pre-Operational Check (Ducting System)		Test No: IQ-05
Objective/Purpose: To provide documented evidence that all ducting has been installed according to the general specification of ductwork installation.		
Pre-requisites: Approved System Handover package is available.		
Method: Verify each aspect of the system installation, as detailed within the results section.		
Acceptance Criteria: The installation of the ducting system complies with the specification of ductwork installation and all mechanical works are as per the latest layout drawing.		
Results:		
Acceptance Criteria	Conformity (Yes/No)	Verified By (Initial & Date)
System installation has been completed according to the ducting layout drawing and all connections have been made.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Inspection for ducting is present and correctness of the tag number for the supply and return air grilles.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Ductwork and bracket are mounted adequately.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Ductwork insulation is correctly installed and properly finished with labels indicating air flow direction. Insulation for cleanliness of the ducting is present.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Probes/pockets/pressure gauges/siphons/orifice plates/taps/vents are installed as specified.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Connections to equipment are correct in relation to design flow direction.	Yes / No	<i>[Signature]</i> 10-Feb-2023
Volume control damper are installed and free to operate.	Yes / No	<i>[Signature]</i> 10-Feb-2023
All components are properly secured.	Yes / No	<i>[Signature]</i> 10-Feb-2023

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Title: Installation Verification - Pre-Operational Check (Ducting System)					
Acceptance Criteria		Conformity (Yes/No)		Test No: IQ-05	
Anti-vibration mountings have precise deflection and all shipping braces have been removed.		Yes / No		10-Feb-2023	
Flushing/ forced circulation cleaning has been completed.		Yes / No		10-Feb-2023	
External cleanliness of AHU.		Yes / No		10-Feb-2023	
Comments/Deviations/Supporting Documentation: NIL					
Overall Test Outcome (PASS/FAIL):		Verified By (Signature):		Date:	
				13 - Feb - 2023.	



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Title:	Installation Verification – HEPA Filter Installation	Test No: IQ-06
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Objective/Purpose:
To provide documented evidence that all HEPA filters have been installed correctly, in good condition and conforms to their target efficiency.

Pre-requisites:
Certificates of conformity for HEPA filters indicate compliance with design specification.

Method:

1. Initiate the system shutdown procedure and confirm electrical isolation. Identify HEPA filter(s) to be installed. Clean filter housing with alcohol taking care to remove all dust and dirt. Allow to dry.
2. To install a new filter, invert box so filter falls from box, minimising physical contact. Record unique reference number and visually inspect filter for any damage. If a test certificate is included, attach this to report. Take filter to housing, remove from bag and carefully smear a thin layer of grease around it to assist insertion. Taking care not to touch the filter media, insert into housing and tighten into place.
3. Repeat steps 1 and 2 for subsequent HEPA filters. Once all HEPA filters have been installed, start-up system and record clean filter pressure drops for information (do this after the air flow design has been achieved).

Acceptance Criteria:
HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process.

AHU/BIBO	HEPA Filter Ref.	Acceptance Criteria	As Found		Verified By (Initial & Date)
		HEPA Filter Grade	HEPA Filter Grade	Visual Inspection Satisfactory (Yes/No)	
AHU-1	THF-01	JAF 1220 X 762 X 69 mm Grade H14	JAF 1220 X 762 X 69 mm Grade H14	Yes/No (Yes)	10-Feb-2023
	THF-02	JAF 1220 X 762 X 69 mm Grade H14	JAF 1220 X 762 X 69 mm Grade H14	Yes/No (Yes)	10-Feb-2023
	THF-03	JAF 305 X 610 X 69 mm Grade H14	JAF 305 X 610 X 69 mm Grade H14	Yes/No (Yes)	10-Feb-2023

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Title:		Installation Verification – HEPA Filter Installation				Test No: IQ-06	
AHU/BIBO	HEPA Filter Ref.	Acceptance Criteria		As Found		Visual Inspection Satisfactory (Yes/No)	Verified By (Initial & Date)
		HEPA Filter Grade		HEPA Filter Grade			
AHU-1	THF-04	JAF 1200 X 600 X 69 mm Grade H14		JAF 1200 X 600 X 69 mm Grade H14		Yes/No	H 10-Feb-2023
	THF-05	JAF 1200 X 600 X 69 mm Grade H14		JAF 1200 X 600 X 69 mm Grade H14		Yes/No	H 10-Feb-2023
	THF-06	JAF 610 X 610 X 69 mm Grade H14		JAF 610 X 610 X 69 mm Grade H14		Yes/No	H 10-Feb-2023
	THF-07	JAF 610 X 610 X 69 mm Grade H14		JAF 610 X 610 X 69 mm Grade H14		Yes/No	H 10-Feb-2023
AHU-2	THF-08	JAF 610 X 610 X 69 mm Grade H14		JAF 610 X 610 X 69 mm Grade H14		Yes/No	H 10-Feb-2023
	HFC-2-01	JAF 610 X 610 X 292 mm Grade H13		JAF 610 X 610 X 292 mm Grade H13		Yes/No	H 10-Feb-2023
BIBO-1	HF-BIBO-1-S1	TROX 610 X 610 X 292 mm Grade H13		TROX 610 X 610 X 292 mm Grade H13		Yes/No	H 10-Feb-2023
	HF-BIBO-1-S2	TROX 610 X 610 X 292 mm Grade H13		TROX 610 X 610 X 292 mm Grade H13		Yes/No	H 10-Feb-2023
BIBO-2A	HF-BIBO-2A	TROX 610 X 610 X 292 mm Grade H13		TROX 610 X 610 X 292 mm Grade H13		Yes/No	H 10-Feb-2023



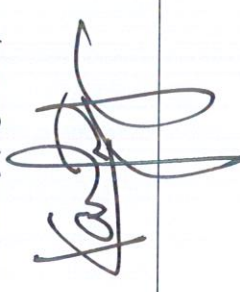
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Title: Installation Verification – HEPA Filter Installation				Test No: IQ-06	
AHU/BIBO	HEPA Filter Ref.	Acceptance Criteria		As Found	
		HEPA Filter Grade	HEPA Filter Grade	Visual Inspection Satisfactory (Yes/No)	Verified By (Initial & Date)
BIBO-3	HF-BIBO-3	TROX 610 X 610 X 292 mm Grade H14	TROX 610 X 610 X 292 mm Grade H14	Yes/No <u>Yes</u>	<u>ft</u> 10-Feb-2023
BIBO-4	HF-BIBO-4	TROX 305 X 610 X 292 mm Grade H13	TROX 305 X 610 X 292 mm Grade H13	Yes/No <u>Yes</u>	<u>ft</u> 10-Feb-2023

Comments/Deviations/Supporting Documentation:

Refer to Filter Inspection Report (Window Documents)

Overall Test Outcome (<u>PASS</u> /FAIL)	Verified By (Signature): 	Date: 13-Feb-2023
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Title:	Installation Verification (System) – Installation Against Drawing	Test No: IQ-07
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Objective:

To provide documented evidence that the mechanical work has been installed according to the approved design layout.

Pre-requisites:

Approved as-built drawing should be attached.

Method:

1. Take a copy of the required drawings to be verified and record the revision numbers in the results table.
2. Compare the drawing against the installation and mark the drawing to clearly indicate areas or items that are correct, that are incorrect and items that could not be verified.
3. Identify the marked-up copy of the drawing with the protocol and test reference then sign and date.

Acceptance Criteria:

The installation of all mechanical work is as per the approved design layout.

Results:

Drawing Title	Ref. No.	Revision No.	Conformity (Yes/No)	Verified By (Initial & Date)
Ductwork Layout (Grand Floor Level)	1 SJMC02 HTL DA HVAC 09	00	Yes/No	10-Feb-2023
Ductwork Layout (Roof Top Floor Level)	L SJMC02 HTL DA HVAC 10	00	Yes/No	10-Feb-2023
	N/A		Yes/No	
			Yes/No	
			Yes/No	



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Title: Installation Verification (System) – Installation Against Drawing					
Comments/Deviations/Supporting Documentation: <i>Refer to attachments</i>					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 13 - Feb - 2023	

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Title:	Installation Verification (System) – Electrical Control Panel	Test No: IQ-08
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Objective:

To provide documented evidence to proof the safety of the control panels and other electrical installations.

Pre-requisites:

Approved electrical control panel drawing should be attached.

Method/Acceptance Criteria/Results:

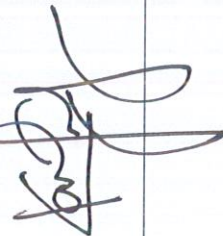
The construction of control panels and other electrical installations complies with the safety standard.

No.	Test Method	Acceptance Criteria	Conformity (Yes/No)	Verified By (Initial & Date)
1	Verify isolator provided.	Isolator provided.	Yes / No	<i>[Signature]</i> 10-Feb-2023
2	Verify the voltage present and supply references are labelled.	Voltage present and supply reference labelled.	Yes / No	<i>[Signature]</i> 10-Feb-2023
3	Verify that the electrical devices are identified.	Electrical devices identified.	Yes / No	<i>[Signature]</i> 10-Feb-2023
4	Verify that an earth strap is fitted in the switchboard.	Earth strap is fitted to the switchboard.	Yes / No	<i>[Signature]</i> 10-Feb-2023
5	Verify that the terminals of electrical components adequately shrouded to prevent contact with live parts.	Terminals of electrical components adequately shrouded to prevent contact with live parts.	Yes / No	<i>[Signature]</i> 10-Feb-2023
6	Verify that main live terminals are adequately shrouded.	Main live terminals are adequately shrouded.	Yes / No	<i>[Signature]</i> 10-Feb-2023
7	Verify that components and wiring are segregated.	Components and wiring are segregated.	Yes / No	<i>[Signature]</i> 10-Feb-2023

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Title:	Installation Verification (System) – Electrical Control Panel	Test No: IQ-08
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Comments/Deviations/Supporting Documentation:
 NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13 - Feb - 2023
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Test No: IQ-09

To provide documented records for all changes made to the system upon installation.

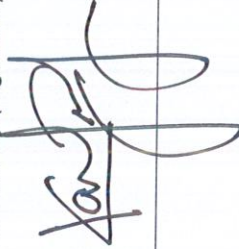
All approved change form must be attached.

1. Record each change made to the system during the completion of the protocol. Record the change reference, a brief description of the change and the date of the change. Clearly and concisely outline what needs to be changed, so the impacted areas can review and analyze.
2. Review the changes made to the system and determine whether further testing is required. If further testing is required determine whether this has been completed satisfactorily.

1. Records for all changes made to the system throughout the execution of this checking procedure are available.
2. Further tests required after the changes made have been conducted.

Results:

[illegible]

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Title:		Test No: IQ-09			
Support – Change Control Record					
Comments/Deviations/Supporting Documentation:					
NIL					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
(PASS/FAIL)				13 - Feb - 2023	

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11.0 SUMMARY OF TEST

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.

Design

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
1	Approved system design documentation is available.	Yes	N/A	10-Feb-2023
2	The data on equipment nameplates is consistent with the design specification.	Yes	N/A	10-Feb-2023

Documentation

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
3	A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.	Yes	N/A	13-Feb-2023
4	Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.	Yes	N/A	10-Feb-2023

Installation

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
5	The installation of the ducting system complies with the specification of ductwork installation and all mechanical works are as per the latest layout drawing.	Yes	N/A	10-Feb-2023
6	HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process.	Yes	N/A	10-Feb-2023
7	The installation of all mechanical work is as per the approved design layout.	Yes	N/A	10-Feb-2023
8	The construction of control panels and other electrical installations complies with the safety standard.	Yes	N/A	10-Feb-2023

Additional

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
9	Records for all changes made to the system throughout the execution of this checking procedure are available and further tests required after the changes made have been conducted.	Yes	N/A	13-Feb-2023

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12.0 TEST INSTRUMENT RECORD

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

N/A
13 Feb 2022

13.0 SIGNATURE RECORD

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

N/A ~~11~~
13-pb-2022



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14.0 INTERIM APPROVAL

This section is only required when all discrepancies in the deviation list have been considered, the HVAC System may proceed for Operational Qualification pending resolution finalization. If there are no discrepancies or all discrepancies found have been suitably resolved, may proceed for Post-Execution Approval.

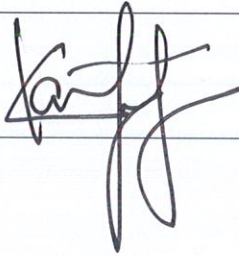
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:			
Reviewed by:		<i>[Signature]</i>	
Approved by:			



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15.0 POST-EXECUTION APPROVAL

CONDITIONAL ACCEPTANCE			
The system operational checks have been reviewed. All testing associated during Installation Qualification are completed with all criteria being met. Any deviations that were noted (if any) have been resolved and closed out.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:		N/A	
Reviewed by:			
Approved by: Stern	Manager		13 - Feb - 2023.



16.0 DEVIATION LIST

Summary of all the deviations documented throughout the execution of the Installation Qualification.

[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:		
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



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

[illegible]