

CERTIFICATE OF COMPLIANCE

ISO CLASS 5 OPERATING THEATRE AIR SYSTEM

Located at: Grace Hospital
281 Cheyne Road
Tauranga

Theatre Reference: Theatre 7

Tests to determine the performance of this operating theatre air system
were carried out on 16-Apr-20

Test procedures and results are summarized as follows:

<u>TEST METHOD</u>	<u>TEST DESCRIPTION</u>	<u>ACCEPTANCE CRITERIA</u>	<u>RESULTS</u>	<u>COMPLIANCE</u>
Based on ISO14644.1:2015	Particle Counting with Automatic Particle	ISO Class 5. Air quality measured under the main diffuser 200mm above the table surface and at periphery	Achieves Requirement	PASS
AS 1807.10	Air Pressure Differentials	Maintain at least positive pressure relative to adjoining rooms except sterile set up rooms	Correct Pressurisation achieved	PASS
AS/NZS ISO 14644.3:2009	Room Air Changes per hour	Air Change Rate > 20 per hour	Exceeds 20 per hour	PASS
AS1807	Temperature RH Sound	Report Only	21.7 °C 61 % 41 dB(A)	Report Only
Air Current Tubes	Air Direction over Operating Table	Downwards Direction	Air flows downwards	PASS
AS1807.3	Velocity/ Uniformity	Report Only	see report Sec 5	Report Only
AS 1807.24	Recovery Time	Report Only	Recovery Time: 3 min	Report Only
AS 1807.6	HEPA Filter Integrity (Optional Test)	< 0.01% Penetration	< 0.01% Penetration	PASS

The results obtained indicate the operating theatre air system complies with performance
requirements as specified in ISO 14644 and AS1668.2:2012

For details refer to Test Report Number: KK20124

Revalidation Due: April-21

Signature: _____

Authorized Signatory: Kwok Keung Fong



LABORATORY ACCREDITATION NO: 535

Unit 30, 930 Great South Road, Penrose, Auckland

All test reported herein have been performed in accordance with the laboratory's scope of accreditation

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Grace Hospital

281 Cheyne Road
Tauranga

Theatre Reference: Theatre 7

ISO Class 5 Operating Theatre Annual Environmental Audit

Test Report No: KK20124

Date of Test: 16-Apr-20

Conducted By: Kwok Keung Fong

Next Test Due: April-21

Signature: _____

A handwritten signature in black ink, appearing to be "Kwok Keung Fong", written over a horizontal line.

Authorized Signatory: Kwok Keung Fong



PERFORMANCE QUALIFICATION REPORT

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Tested by: Kwok Keung Fong

Checked by:

S. Charters

Date:

17/04/2020

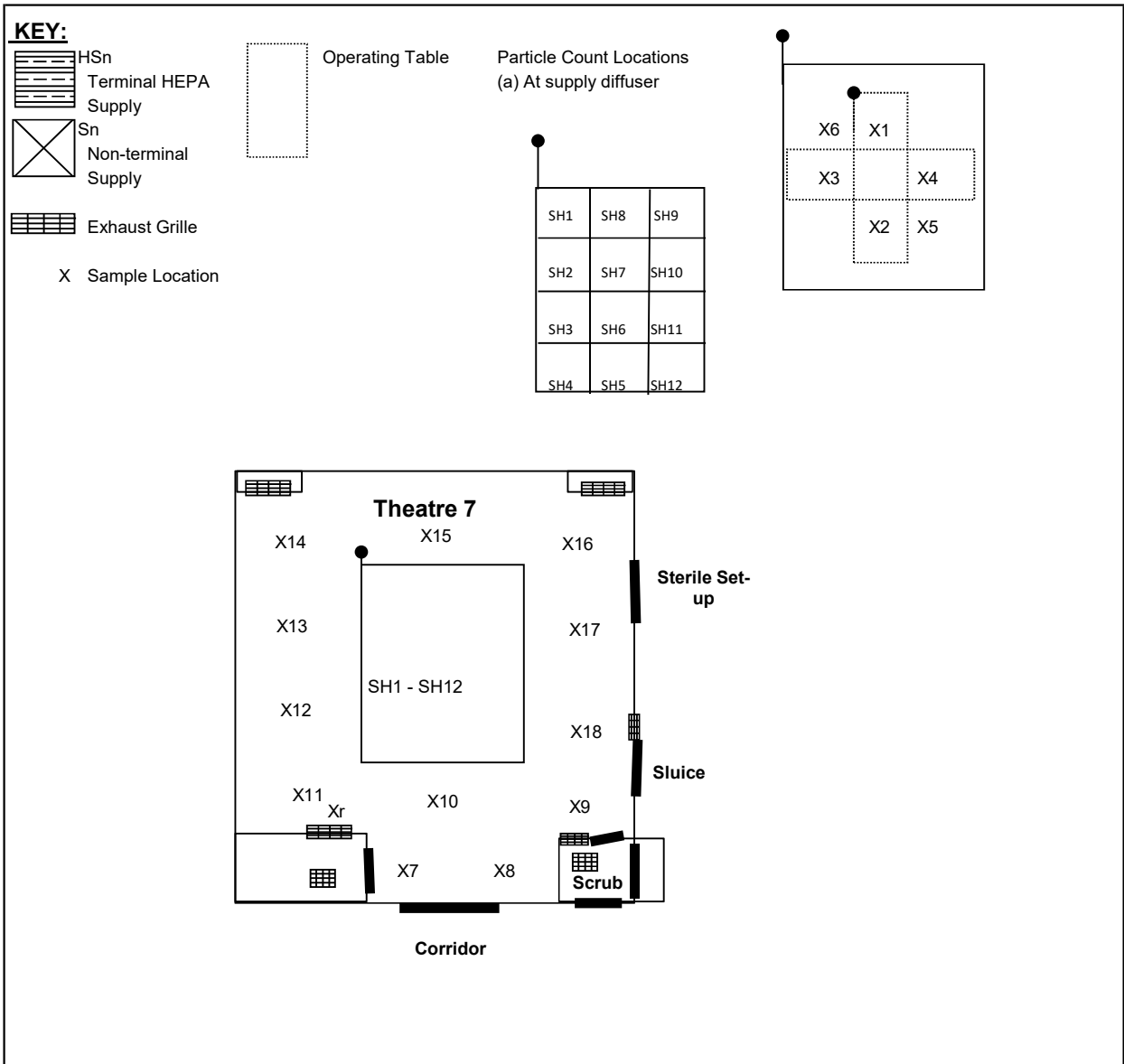


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FACILITY LAYOUT



Tested by: Kwok Keung Fong

Checked by: S. Hartens

Date:

17/04/2020



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AIR QUALITY - ISO CLASS 5

AREA Main Supply Air Diffuser and Operating Table

TEST SPECIFICATION Particle Counting in work zone using automatic particle counter by test method based on ISO 14644-1:2015

REQUIREMENT Maximum number particles ≥ 0.5 micron per m^3 of air = 3,520
Maximum number particles ≥ 1.0 micron per m^3 of air = 832

SAMPLING PARAMETERS

Area Status: at rest Personnel Loading: 0 Equipment Loading: Yes
 Sample Rate: 1.77 cubic foot per min = 0.8334637 litres per second
 Sample Volume: 50 litres Or Sample Time: 60 sec

RESULTS

Sample Location	No. of Samples	Average Counts $\geq 0.5 \mu$	Average Concentration (per m^3)	Sample Location	No. of Samples	Average Counts $\geq 1.0 \mu$	Average Concentration (per m^3)
(a) Particle Counting at Main Air Supply Diffuser				(a) Particle Counting at Main Air Supply Diffuser			
5	1	0	0	5	1	0	0
6	1	0	0	6	1	0	0
Max Particles/ $m^3 \geq 0.5$ micron: 0				Max Particles/ $m^3 \geq 1.0$ micron: 0			
Sample Location	No. of Samples	Average Counts $\geq 0.5 \mu$	Average Concentration (per m^3)	Sample Location	No. of Samples	Average Counts $\geq 1.0 \mu$	Average Concentration (per m^3)
(b) Particle Counting above Table				(b) Particle Counting above Table			
1	1	1	20	1	1	1	20
2	1	0	0	2	1	0	0
3	1	6	120	3	1	2	40
4	1	2	40	4	1	2	40
Max Particles/ $m^3 \geq 0.5$ micron: 120				Max Particles/ $m^3 \geq 1.0$ micron: 40			

RESULT: PASS

COMMENTS:

Instrument Used: Particle Counter: CFN-138 Calibration Due: 26 November 2020

Tested by: Kwok Keung Fong

Checked by: *S. Hartman*

Date: _____

17/04/2020



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AIR QUALITY - ISO CLASS 7

AREA Peripheral Air Supplies & Background

TEST SPECIFICATION Particle Counting in work zone using automatic particle counter by test method based on ISO 14644-1:2015

REQUIREMENT Maximum number particles ≥ 0.5 micron per m^3 of air = 352,000
 Maximum number particles ≥ 5.0 micron per m^3 of air = 2,930

SAMPLING PARAMETERS

Area Status: at rest Personnel Loading: 1 Equipment Loading: Yes
 Sample Rate: 1.77 cubic foot per min = 0.8334637 litres per second
 Sample Volume: 50 litres Or Sample Time: 60 sec

RESULTS

Sample Location	No. of Samples	Average Counts ≥ 0.5 u	Average Concentration (per m^3)	Sample Location	No. of Samples	Average Counts ≥ 5.0 u	Average Concentration (per m^3)
(a) Particle Counting at Peripheral Air Outlets				(a) Particle Counting at Peripheral Air Outlets			
No Theatre room	1				1		
	1				1		
	1				1		
Max Particles/ $m^3 \geq 0.5$ micron:				Max Particles/ $m^3 \geq 5.0$ micron:			
Sample Location	No. of Samples	Average Counts ≥ 0.5 u	Average Concentration (per m^3)	Sample Location	No. of Samples	Average Counts ≥ 5.0 u	Average Concentration (per m^3)
(b) Particle Counting in Room Periphery				(b) Particle Counting in Room Periphery			
7	1	421	8420	7	1	74	1480
8	1	241	4820	8	1	46	920
9	1	362	7240	9	1	76	1520
10	1	45	900	10	1	8	160
11	1	347	6940	11	1	82	1640
12	1	154	3080	12	1	47	940
13	1	39	780	13	1	8	160
14	1	236	4720	14	1	51	1020
15	1	584	11680	15	1	123	2460
16	1	669	13380	16	1	111	2220
17	1	504	10080	17	1	112	2240
18	1	549	10980	18	1	85	1700
Max Particles/ $m^3 \geq 0.5$ micron:				Max Particles/ $m^3 \geq 5.0$ micron:			
			13380				2460

RESULT: PASS

COMMENTS:

Tested by: Kwok Keung Fong

Checked by: *S. Chaitum*

Date:

17/04/2020



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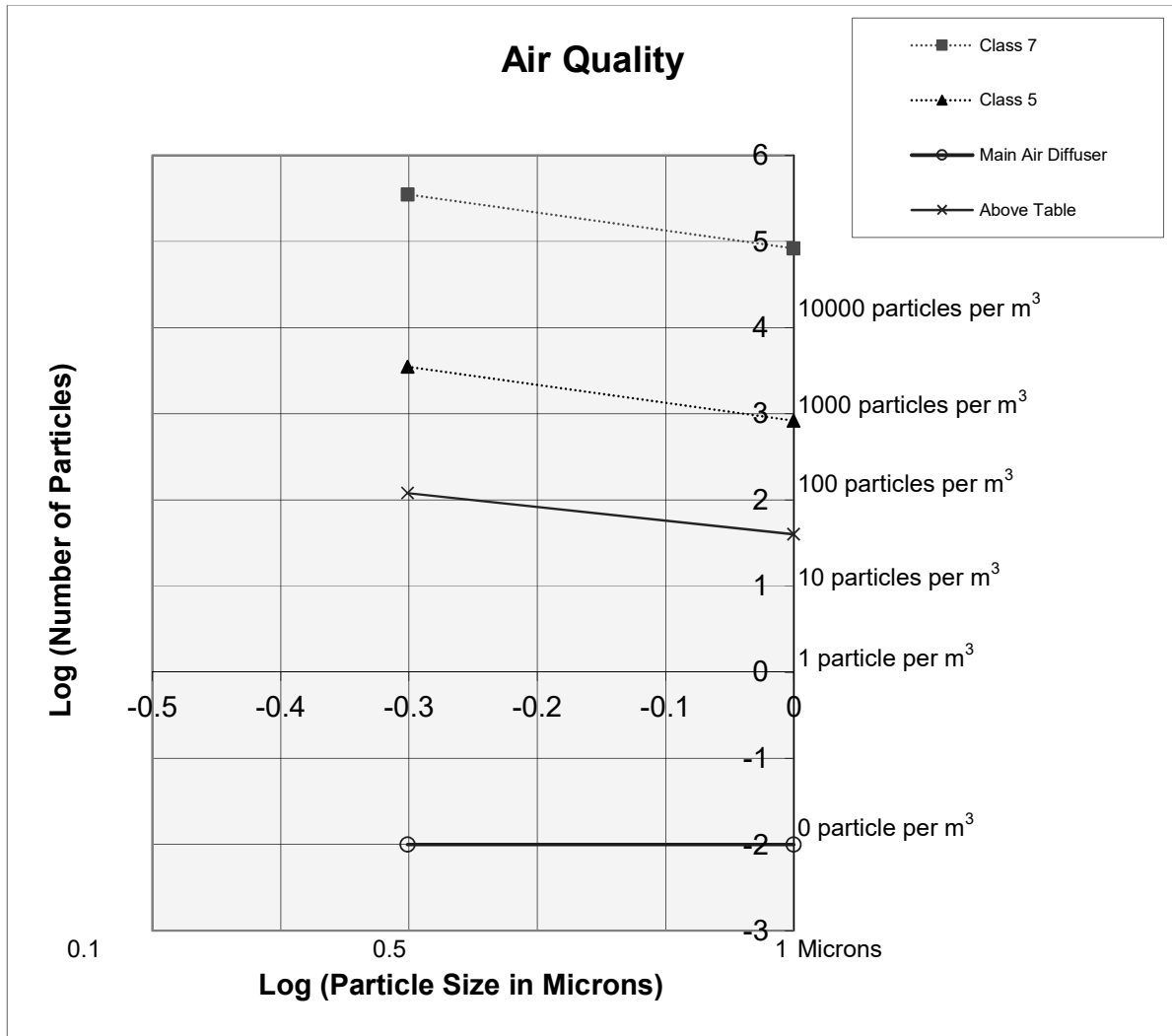
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AIR QUALITY - ISO CLASS 5

GRAPHICAL REPRESENTATION OF PARTICLE COUNT RESULTS

Main Supply Air Diffuser and Operating Table



Note: A zero particle count is shown as 0.01particles per litre for purposes of this graph.

Tested by: Kwok Keung Fong

Checked by:

S. Hartens

Date:

17/04/2020



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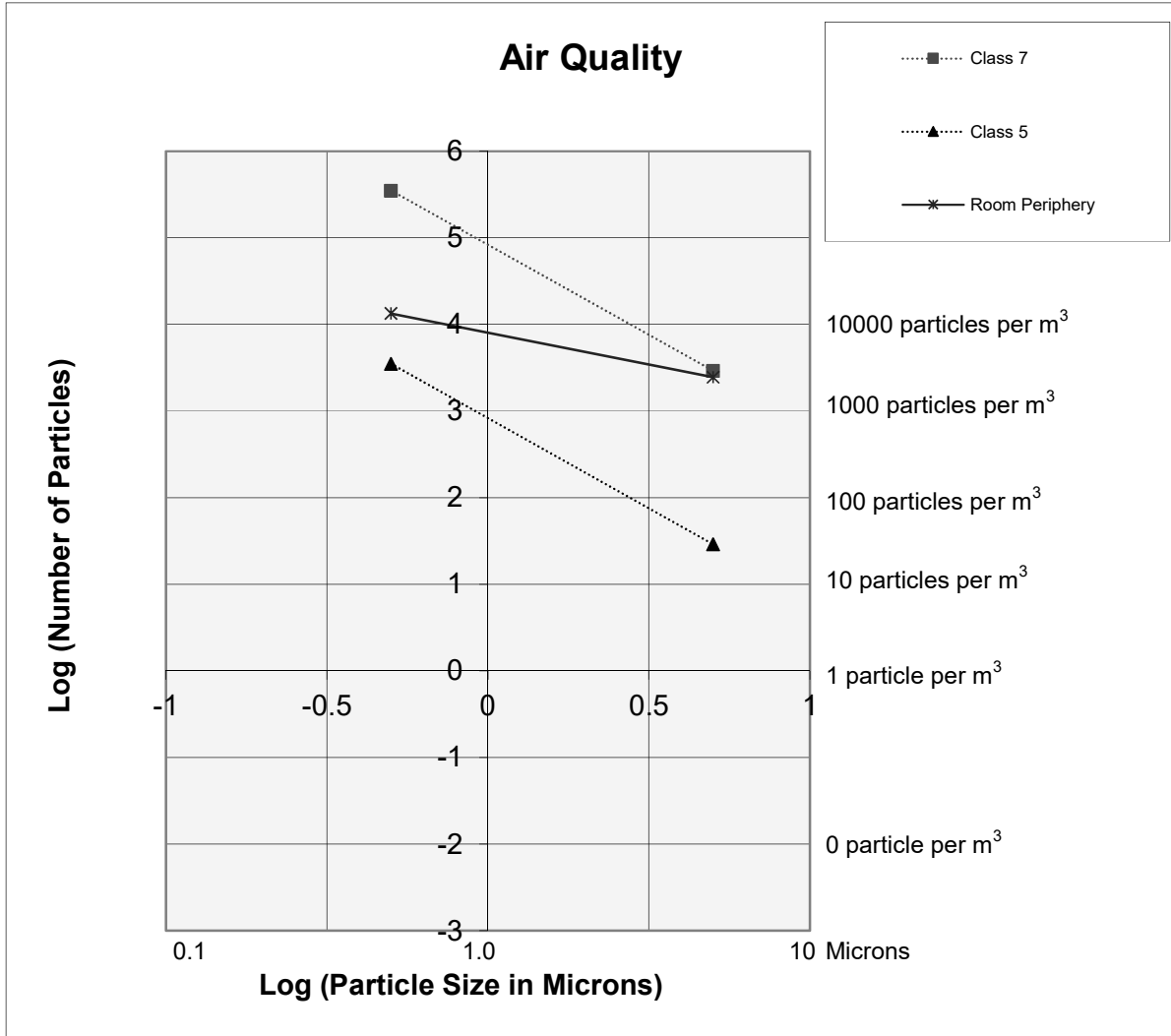
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AIR QUALITY - ISO CLASS 7

GRAPHICAL REPRESENTATION OF PARTICLE COUNT RESULTS

Room Periphery



Tested by: Kwok Keung Fong

Checked by:

S. Charters

Date:

17/04/2020



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AIR PRESSURE DIFFERENTIALS

AREA Theatre 7

TEST SPECIFICATION Determination of Air Pressure of Cleanrooms by AS1807.10 test method.

REQUIREMENT The theatre shall be at least positive pressure to all adjacent areas (except for a Sterile Prep area with HEPA filtered air supply) when all doors are closed.

RESULTS

Zone	Pressure Relative to Adjacent Zone			Adjacent Zone	Pass/Fail
	Required (Pa)	Measured (Pa)	Wall Gauge (Pa)		
Theatre	+ve	6	N/A	Corridor	PASS
Theatre	+ve	13	N/A	Sluice Room	PASS
Theatre	-ve	-2	N/A	Sterile Setup Room	PASS

COMMENTS:

Instrument Used: Manometer CFN-225

Calibration Due: 30 June 2022

Tested by: Kwok Keung Fong

Checked by: *S. Chentim*

Date: 17/04/2020



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MAIN DIFFUSER AIR VELOCITY AND UNIFORMITY

FILTER REFERENCE(S) SH1-SH12

TEST SPECIFICATION Determination of Air Velocity and uniformity in laminar flow cleanrooms by AS 1807.3 test method with air system in cooling cycle.

REQUIREMENT Report Only

RESULTS

Initial					
0.28	0.26	0.24			
0.20	0.30	0.24			
0.23	0.24	0.27			
0.24	0.28	0.27			

Average Velocity: 0.25 m/s
 Maximum Velocity: 0.3 m/s 20%
 Minimum Velocity: 0.20 m/s -20%

Initial					
0.28	0.26	0.24			
0.21	0.27	0.24			
0.23	0.24	0.27			
0.24	0.28	0.27			

Average Velocity: 0.25 m/s
 Maximum Velocity: 0.28 m/s 12%
 Minimum Velocity: 0.21 m/s -16%

COMMENTS: Measurements taken with hot-bead anemometer per Health Technical Memorandum 2025. The rotary vane anemometer prescribed by AS 1807.3 is not appropriate due to non-parallel airflow.

Result is used to calculate Air change rate (page 6-1)

Instrument Used: Anemometer CFN-210

Calibration Due: 20 November 2020

Tested by: Kwok Keung Fong

Checked by: S. Charters

Date:

17/04/2020



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AIR CHANGE RATE

AREA Theatre 7

TEST SPECIFICATION Determination of Air Change Rate by ISO 14644.3:2009 test method

REQUIREMENT The minimum number of air changes per hour is 20.

DETERMINATION OF AIR VOLUME Via average velocity by AS/NZS 14644.3:2009, B.4.3.3

RESULTS

Air Change Rate / hr = Air Supply Volume(m ³ /sec)x3600 / RoomVolume (m ³)							
Room Details		Air Supply Diffuser Details				Air Change rate	
Identification	Vol (m ³)	Supply Ref	Face Area (m ²)	Air Velocity Measured (m/s)	Air Volume Measured (m ³ /s)	No.	Pass/Fail
Theatre	218	SH1	0.58	0.28	0.16	29	PASS
		SH2	0.58	0.21	0.12		
		SH3	0.58	0.23	0.13		
		SH4	0.58	0.24	0.14		
		SH5	0.58	0.28	0.16		
		SH6	0.58	0.24	0.14		
		SH7	0.58	0.27	0.16		
		SH8	0.58	0.26	0.15		
		SH9	0.58	0.24	0.14		
		SH10	0.58	0.24	0.14		
		SH11	0.58	0.27	0.16		
		SH12	0.58	0.27	0.16		
		Total	7.0				

COMMENTS: Measurements taken with hot-bead anemometer per Health Technical Memorandum 2025. The rotary vane anemometer prescribed by AS 1807.3 is not appropriate due to non-parallel airflow.

Required Theatre Supply Air volume to achieve 20 Theatre Air changes/hour: 1.21 m³/s

Instrument Used: Anemometer CFN-210

Calibration Due: 20 November 2020

Tested by: Kwok Keung Fong

Checked by:

Date:

17/04/2020



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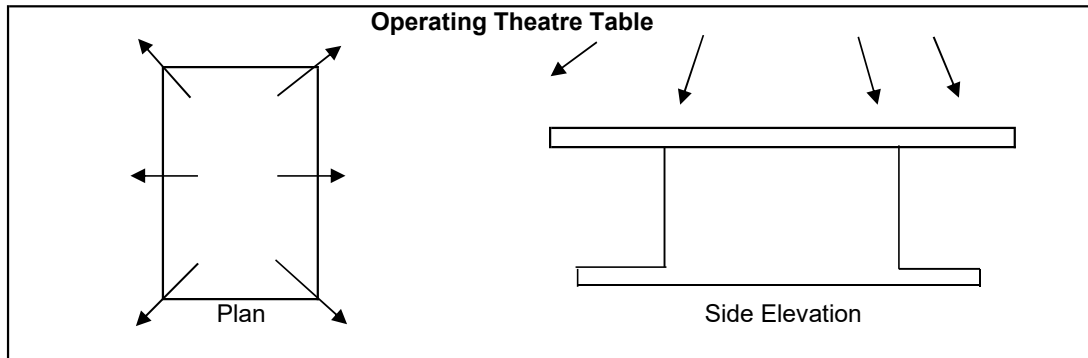
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AIR FLOW DIRECTION, TEMP, RH & SOUND

AREA	Theatre 7
TEST SPECIFICATION	Determination of Air Flow Direction using Air Current Tubes. Determination of air temperature and relative humidity.
REQUIREMENT	Airflow direction at 200mm above the operating table surface shall be downwards when theatre lights are in their normal position.

RESULTS

Air Flow Direction:



Compliance: Pass

Temperature, Relative Humidity & Sound Level:

Above Operating Table:		At Exhaust:	
Sample Location:	X2	Sample Location:	Xr
Temperature:	21.7 °C	Temperature:	21.7 °C
Relative Humidity:	61 %	Relative Humidity:	61 %
Sound Level:	41 dB(A)		

COMMENTS: Smoke test was recorded and recording left with the customer

Instrument Used: Sound Meter CFN-228
Instrument Used: Hygo-thermometer CFN-189

Calibration Due: 9 September 2020

Tested by: Kwok Keung Fong

Checked by: *B. Chantins*

Date:

17/04/2020



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PERFORMANCE QUALIFICATION REPORT

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RECOVERY TIME

AREA Theatre

TEST SPECIFICATION Determination of Recovery Time of cleanroom using AS1807.24 test method.

REQUIREMENT Report Only

RESULTS

Aerosol Release Location	Air Supply Grilles
Air Particulate Sample Location	Location Xr
Air Sample Rate (l/s)	50
Aerosol Release Duration (min)	

Total particles counted in 1 minute	
Time (minutes from start)	≥ 0.5 Micron
0	460
1	11866
2	5363
3	2457
4	1075
5	633
6	501
7	503
8	436

Particles per minute	≥ 0.5 Micron
Initial Room "At Rest"	460
High Particle Concentration Level at time	5363 2
Low Particle Concentration Level at time	633 5
Recovery Time (min)	3

COMMENTS: The recovery time is the recovery time of the whole theatre, and not of the laminar flow section of the theatre. The test method used is that applicable to the non-laminar flow part of the room.

DEVIATION: Excess particles were not generated from aerosol generator.

Tested by: Kwok Keung Fong

Checked by: S. Charters

Date: 17/04/2020



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PERFORMANCE QUALIFICATION REPORT

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AIR VELOCITY / TERMINAL HEPA FILTER INTEGRITY

ROOM: Theatre 7

TEST SPECIFICATION Determination of Air Velocity by AS1807.1 or AS1807.3 or otherwise.
Determination of integrity of terminal mounted HEPA filter installations by AS1807.6 test method.

REQUIREMENT The penetration of the HEPA filter installation shall not exceed 0.01%

RESULTS

Filter Ref & Size mxm	No. Laskin Nozzles	Initial Results		Final Results			Integrity Pass/Fail
		Velocity m/s	Pressure Pa	Velocity m/s	Pressure Pa	Leaks?	
REF SH1 0.87 0.67	1	0.55 319 L/sec	-	0.55 319 L/sec	-	No Leaks	Pass
REF SH2 0.87 0.67	1	0.52 302 L/sec	-	0.52 302 L/sec	-	No Leaks	Pass
REF SH3 0.87 0.67	1	0.47 273 L/sec	-	0.47 273 L/sec	-	No Leaks	Pass
REF SH4 0.87 0.67	1	0.48 279 L/sec	-	0.48 279 L/sec	-	No Leaks	Pass
REF SH5 0.87 0.67	1	0.51 296 L/sec	-	0.51 296 L/sec	-	No Leaks	Pass
REF SH6 0.87 0.67	1	0.55 319 L/sec	-	0.55 319 L/sec	-	No Leaks	Pass
REF SH7 0.87 0.67	1	0.44 255 L/sec	-	0.44 255 L/sec	-	No Leaks	Pass
REF SH8 0.87 0.67	1	0.43 250 L/sec	-	0.43 250 L/sec	-	No Leaks	Pass
REF SH9 0.87 0.67	1	0.42 244 L/sec	-	0.42 244 L/sec	-	No Leaks	Pass
REF SH10 0.87 0.67	1	0.44 255 L/sec	-	0.44 255 L/sec	-	No Leaks	Pass
REF SH11 0.87 0.67	1	0.46 267 L/sec	-	0.46 267 L/sec	-	No Leaks	Pass
REF SH12 0.87 0.67	1	0.55 319 L/sec	-	0.55 319 L/sec	-	No Leaks	Pass

oo indicates leaks not sealed

xx indicates leaks sealed

Comment Fan was running at 50 Hz during the testing

Instrument Used: Generator CFN-025

Calibration Due: 21 May 2020

Instrument Used: Photometer CFN-226

Calibration Due: 10 June 2020

Tested by: Kwok Keung Fong

Checked by: S. Charters

Date:

17/04/2020



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