

EQUIPMENT PERFORMANCE REPORT

Ref: 20200722-R01



PROJECT ATA DOPAIR MULTIZONE PERFORMANCE TEST

		السبت تنقية الدر
Date	PREPARED BY	THE DUBAL-U.A.E. *
22 Jul 2020	Rayan ZAKHOUR	BINAIR WIDDLE EAST AIR FILTRAMON LS

Aspecmembre

IGIENAIR MIDDLE EAST 711, LAKE CENTRAL TOWER BUSINESS BAY, DUBAI, UAE



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1. CONFIDENTIALITY

All information about the audited spaces, their plans, and any other document related to this project are confidential. This report is also confidential and shall not be shared with any other party unless clearly authorized by the client. This report is the property of IGIENAIR and shall not be reproduced without written approval from IGIENAIR.

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2. SCOPE DEFINITION

2.1. Purpose

The purpose of this job is to evaluate the performance on the DOPAIR MULTIZONE AIR PURIFIER in a typical clean room. As per the requirements of PO 4412 from ATA.

This is done by comparing the particle contamination level in the room with and without the purifier in operations. Then a data comparison will be done to highlight the improvement on the air quality when the air purifier is in operation. See the unit serial number in photos below.



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2.2. Compliance

Local authorities					
□ DHCC	□ DHA		□ DOH		
□ Others					
Applicable norms and standards					
☑ Client requirements	⊠ ISO 14	644 🗆 USP 800			
□ ASHRAE STD 170	\Box CCFR.	A	□ USP 797		
□ GMP 2008	USFD.	A	□ NIOSH		
Qualifications phase					
□ IQ (Installation)					
□ OQ (Operational)					
□ PQ (Performance)					
Qualifications frequency					
□ Monthly qualifications	\Box Monthly qualifications \blacksquare Others : One time.				
□ Quarterly qualifications					
□ Annual Qualifications					
External sourcing		Selected laborator	у		
□ Microbiological air sampling	□ WIMPEY				
□ Microbiological surface sampling		□ Other			
□ Microbiological incubation and a	malysis				
□ Other					

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2.3. Test references

All tests results were evaluated as per below standards, unless stated otherwise on test results sheets.

Execution of tests will be made in compliance with applicable standards. When standards are not specific, tests will be done following IGIENAIR internal procedures.

IGIENAIR keeps its right to change the order of tests based on site conditions to avoid delays of the project.

Tests	Standard	Applicable			
AERAULIC P	AERAULIC PARAMETERS				
Airflow laminarity	ISO 14644-1				
Air flow rates	ASHRAE STD 170				
Air Changes Rate	ASHRAE STD 170				
Rooms differential pressure	ASHRAE STD 170				
Air flow visualization	-				
AIR CLEANLINESS LEVEL					
Particle count	ISO 14644-1	\checkmark			
HEPA & ULPA FILTER INTEGRITY TESTS					
Filter installations	VISUAL				
Filter integrity test using EMERY	ISO 14644-3				
MICROBIOLOGY TESTS					
SURFACE SAMPLING	USFDA-CCFRA				
AIR SAMPLING	NIOSH				

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2.4. ISO CLEANROMM CLASSIFICATION

Cleanrooms are classified according to the cleanliness level of the air inside them. The cleanroom class is the level of cleanliness the room complies with, according to the quantity and size of particles per volume of air. ISO classification system is ISO 14644-1. This standard includes the cleanroom classes ISO 1, ISO 2, ISO 3, ISO 4, ISO 5, ISO 6, ISO 7, ISO 8 and ISO 9, with ISO 1 being the "cleanest" and ISO 9 the "dirtiest" class (but still cleaner than a regular room). The most common classes are ISO 7 and ISO 8. The table below indicates the maximum concentration of particles of different sizes in each ISO class.

ISO classification number (<i>N</i>)	Maximum concentration limits (particles/m ³ of air) for particles equal to and large than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
number (N)	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	:10	2			:	
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

Table 1 - Calested airborne	particulate cleanlineer clary	ses for cleanrooms and clean zones
Table I - Selected all bottle	particulate cleaniness class	ses for clean coms and clean zones

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1.1. Test conditions

Unless stated otherwise all tests were done per conditions listed in the table below and as per the following definitions:

At rest : Installations completed and equipment running with no personnel present.

In operation : Installations completed and equipment running. Personnel present and working as per regular procedures

Tests	Conditions	Applicable	
AERAULIC PAR	RAMETERS		
Airflow laminarity	At rest		
Air flow rates	At rest		
Air Changes Rate	At rest		
Rooms differential pressure	At rest		
Air flow visualization At rest			
AIR CLEANLIN	ESS LEVEL		
Particle count At rest; 0.5 µm; 1.0 µm; 5.0 µm.		\checkmark	
HEPA & ULPA FILTER	INTEGRITY TESTS		
Filter installations	Visual		
Filter integrity test EMERY			
MICROBIOLOGY TESTS			
Surface sampling	At rest		
Air sampling	At rest		

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2. REPORT PARTICULARS

2.1. Validity

This report defines the performance at the time of testing.

The results are shown compliant or non-compliant as per above mentioned criteria.

This report is only valid for the tested rooms.

2.2. Special notes

The test was done on the unit performance as a whole and is not a filter classification report nor a validation of its design.

2.3. Color coding

All test results will be color coded as follows

COMPLIANT	(C)
COMPLIANT BUT ON THE LIMIT OF ACCEPTABLE RANGE.	(C/L)
NON COMPLIANT	(NC)

For more details see document IGIENAIR - ACC-DOC-021

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3. TESTING

3.1. Methodology and results.

Setup

The air purifer was placed at the center of an operation theatre show room with the following dimension: L 5.6m, W 4.8m, H 2.9. The total volume of the room is approximately 78 cubic meters. The air purifier was set to the highest fan speed, hence 800 cubic meters per hour yielding approximately 10 air changes per hour.

A particle counter was placed at a representative location in the room.

The room was evacuated to perform the testing at rest.

The HVAC system in the room was turned off.

First particle count - Air purifier off.

In the first phase of measurements, the air purifier was off and 20 samples of 50 liters each were taken (1 min sampling as a minimum sampling as per ISO 14644) as per the standard procedure ISO 14644. The total duration of the sampling was 40 minutes. The readings showed a steady concentration of particles in the room.

The concentration level was in the ISO 9 Class.

Second particle count - Air purifier on.

In the first phase of measurements, the air purifier was turned on and 20 samples of 50 litres each were taken (1 min sampling) as per the standard procedure ISO 14644. The total duration of the sampling was 40 minutes. The readings showed a decrease of concentrations of particles in the room to reach ISO 8 level after 30 minutes of operation.

Room class improved from ISO 9 to ISO 8 in approximately 30 minutes.

And the concentrations kept going down for the whole duration of the sampling and after 40 minutes, the particle removal rates were:

- 0.5 Microns 52% eliminated
- 1.0 Microns 51% eliminated
- 5.0 Microns 65% eliminated

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3.2. Particle counter data

	0.	5 MICRONS			1.0 MICRONS	5		5.0 MICRON	S
	ISO 8	Dopair off	Dopair on	ISO 8	Dopair off	Dopair on	ISO 8	Dopair off	Dopair on
то	3,520,000	4,017,160	3,862,380	832,000	1,540,900	1,496,660	29,300	9,400	5,040
T2	3,520,000	3,996,420	3,683,560	832,000	1,540,360	1,434,160	29,300	9,720	5,180
T4	3,520,000	4,061,380	3,500,960	832,000	1,564,380	1,358,400	29,300	8,380	4,640
Т6	3,520,000	4,031,520	3,259,900	832,000	1,557,040	1,265,980	29,300	8,760	3,920
Т8	3,520,000	4,029,280	3,134,180	832,000	1,546,120	1,212,960	29,300	8,800	4,000
T10	3,520,000	4,016,660	2,998,040	832,000	1,541,980	1,163,980	29,300	8,440	3,260
T12	3,520,000	4,033,060	2,853,600	832,000	1,545,540	1,100,600	29,300	7,400	3,780
T14	3,520,000	4,050,140	2,757,860	832,000	1,549,540	1,063,700	29,300	6,920	3,200
T16	3,520,000	4,013,100	2,629,220	832,000	1,533,060	1,019,580	29,300	6,500	3,120
T18	3,520,000	4,031,740	2,546,940	832,000	1,542,800	986,120	29,300	6,680	2,560
T20	3,520,000	4,005,940	2,447,220	832,000	1,536,180	953,620	29,300	6,400	2,700
T22	3,520,000	4,030,420	2,396,340	832,000	1,548,140	930,620	29,300	6,960	2,620
T24	3,520,000	3,990,100	2,301,660	832,000	1,520,320	899,460	29,300	7,140	2,520
T26	3,520,000	4,041,940	2,218,720	832,000	1,549,300	866,780	29,300	5,560	2,400
T28	3,520,000	4,064,300	2,128,540	832,000	1,553,560	828,040	29,300	6,280	2,140
T30	3,520,000	4,088,400	2,109,080	832,000	1,580,060	825,180	29,300	4,980	2,060
T32	3,520,000	4,097,040	2,027,900	832,000	1,583,740	801,460	29,300	5,840	1,580
T34	3,520,000	4,109,000	1,960,180	832,000	1,589,280	769,180	29,300	5,380	2,060
T36	3,520,000	4,198,860	1,917,620	832,000	1,631,280	760,360	29,300	5,500	1,760
T38	3,520,000	4,237,780	1,864,920	832,000	1,650,000	732,440	29,300	5,320	1,780
avera	ge	4,057,212	2,629,941		1,560,179	1,023,464		7,018	3,016
reduc	tion	-	52%		-	51%		-	65%

Concentration in particles per cubic meter.

Values in red do not meet ISO 8 LEVEL.

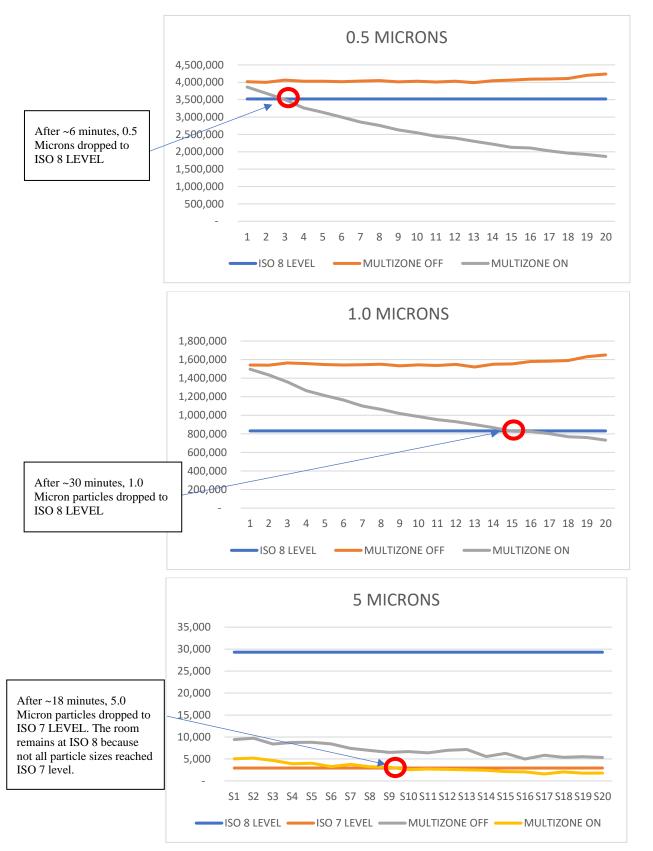
Values in green meet ISO 8 LEVEL.

T0: First sample. T38: 20th sample. approximately at minute 38.

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3.3. Charts



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4. CONCLUSION.

The performance check was done in a 26 square meters, 78 cubic meters operating theatre in a medical center in Dubai, UAE. Since our goal was to check the performance of the air purifier and not to perform a full classification of the room, sampling was done in one location only.

Room ISO class improved from ISO 9 to ISO 8 in 30 minutes.

As the unit kept running, the air quality kept improving and the particle concentrations kept dropping through all the 40 minutes of sampling. At the end of 40 minutes, a reduction of particles as follows was noted.

0.5 Microns 52% eliminated

1.0 Microns 51% eliminated

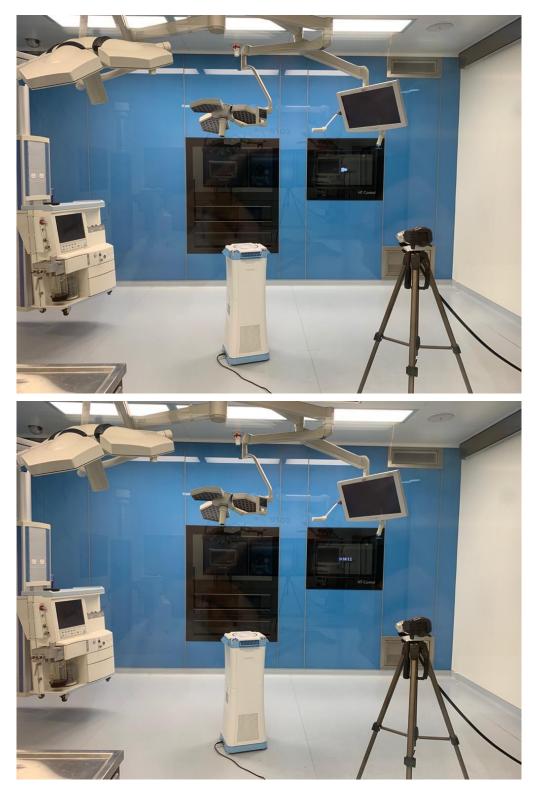
5.0 Microns 65% eliminated

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5. ANNEXES

5.1. Annex A - Photos



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5.2. Annex B – Particle count tickets

New Property Control of the Property of the Pr	
PEOCRAM:	PROCERM-
10-47A DOPAIR OFF 21/47/28	18- ata bopatr on
Sample Vol- SBL SAMPLEN = 1 COUNTS/CH	Sample Vol- Sel Samples 1 Counts/CH
TIME 9-5 31.0 55.8 FLOW	Time 28-5 11-8 55.8 Flow
10:24:04 4017160 1549900 5400 51.0	11:05:02 3052308 1496668 5040 51.0
PBOCRAM:	PROCRAM-
10: ATA BOPAIR OFF 21/97/28	18= ATA DOPAIR ON 21/87/28
Sample Vol:- SHL Samples 2 CountS/CH	SAMPLE VOL- SAL SAMPLE#= 2 COUNTS/CM
TIME 94.5 31.8 55.8 FLGH	TINE 28.5 31.8 35.8 FLOU
10:26:03 395428 1540360 9728 51.0	11:87:81 3683568 1434168 5188 58.5
PROGRAM:	PROGRAM-
1D= ATA DOPAIR OFF 21/47/28	10= ATA DOPAIR ON 21/07/20
SAMPLE VOL= SHL SAMPLEB= 3 CONTS/CM	SAMPLE VOL SAL SAMPLEN= 3 COUNTS/CM
TIME 3-5.5.8 FLOA	11KE 20.5 31.0 35.8 FLOM
18:28:28 4851388 1564388 8388 51.8	11:09:00 3500306 1350400 4640 51.0
PROCRAM-	PROGRAM-
1D- ATA BOPAIR OFF 21/47/28	10= ATA DOPAIR ON 21/87/28
Sample Vol= Sel Samples 4 Counts/CM	SAMPLE VOL= SAL SAMPLEB= 4 COUNTS/CM
TTME 9-5 31.0 35.8 FLOA	TIME >8.5 >1.8 >5.8 FLOM
10:30:81 4031528 1557840 8768 51.0	11:18:59 3259988 1265988 3928 51.8
PEOGRAM: 1D-418 EOPAIR OFF 21/87/28 Sample VOL- SHL SAMPLEN 5 COUNTS/CH TIME 3-5 31.0 55.8 FLOW 10:32:00 4025280 1546120 8000 51.0	PROCRAM= 21/87/28 ID= ATS BOPAIR ON 21/87/28 SAMPLE VOL= S&L SAMPLE#= 5 COUNTS/CM TIME TIME 38.5 31.8 11:12:58 3134188 1212968 4888
PBOCRAM:	PROCEAN-
10= ATA DOPAIR OW=1-	13- 6TA BOPAIR ON 21/07/28
SAMPLE VOL= 50. SAMPLE= 6 CONTS/CH	SAMPLE VOL- SEL SAMPLES- 6 COUNTS/CM
TIME 9-5 71.6 75.8 FLOW	TIME 38.5 31.8 35.8 FLOW
10:33:59 4016660 1541900 8440 51.0	11:14:57 295844 1163988 3266 58.5
PROCRAM-	PROCRAM: 21/07/28
13- ATA BOPAIR OUT TT 21/87/28	18: ATA BOPAIR ON 21/07/28
SAMPLER VOL- SEL SAMPLER 7 CONTS/CM	SAMPLE VOL= SEL SAMPLES: 7 COUNTS/CM
TIME 36, 5 1.1.8 75.8 TLOW	TIME 38.5 31.8 35.8 FLOM
18:35:58 4833868 1545548 7488 51.8	11:16:156 2833688 1188688 3788 58.5
P20CBAM= 10= 818 D0P412 00P=™ 21/87/28 SAMPLE UOL= SEL SAMPLE# 8 CONTS/CM TIME 38.5 31.8 35.8 TLOW 18:37:37 458144 1549548 6328 51.8	PROCEAM= 21/87/28 1B= ATA DOPAIR ON 21/87/28 SARPLE VOL= SEL SAMPLES 8 COUNTS/CM TIME 38.5 31.8 35.8 11:18:55 2757868 1863768 3288 58.5
	PROCRAM: 21/87/28 ID= ATS BOPAIR ON 21/87/28 Sample Vol= 501 Samples 9 Counts/CM Time 30.5 31.8 35.8 Flow 11:28:54 2629228 1819508 3128 50.5
PROCRAM- 10= ATA DOPAIR ONFT- SHPLL VOL. SEL SAMPLEN-18 COUNTS/CM SHPLL VOL. 91.5 VI.8 VS.8 FLOH TIME 98.5 VI.8 VS.8 FLOH TIME 98.5 SA 5	11:22:53 2345948 985128 2368 38.3
14:41:55 4431/40 1542480 0000 17/17 10-478 007817 08=75 21/47/28 SAMTLE VOL- SEL SAMPLIN= 11 COUNTS/CR TIME 38.5 21.8 35.6 18 18:43:54 448594 1556188 6488 51.8	PROCRAM= 21/87/28 ID= ATA DOPAIR ON 21/87/28 SAMPLE VOL= S&L SAMPLES= 11 COUNTS/CM TIME 36.5 31.8 35.8 T11E 36.5 31.8 35.8 FLOW 11:24:52 2447228 953628 2788 56.5
	PROCRAM- ID- 6TA BOPAIR ON 21/87/28 SAMPLE VOL- 581 SAMPLEN- 12 COUNTS/CM TIME 38.5 31.0 55.8 FLOM 11:26:51 2396348 938628 2628 58.5
PROCEAM:	PROCRAM-
10= ATE BOPAIR ONFOF	1D= ATA BOPAIR ON 21/87/28
SAMPLE VOL- SEL SAMPLEN= 13 COUNTS/CH	SAMPLE VOL= 581 SAMPLEN= 13 COUNTS/CM
TIME 10.5 31.8 35.8 TLON	TIME 38.5 31.8 75.8 FLOM
18:47:52 3598188 1528228 7148 51.8	11:28:58 2381668 893468 2528 51.8
PROCRAM-	PBOCRAM-
13- ATA DOPAIR ONF-P: 21/07/28	10- ATA DOPAIR ON 21/07/28
SAMPLER VOL- S9L SAMPLEN= 14 CONTS/CM	SAMPLE VOL= SEL SAMPLER- 14 COUNTS/CM
TIME 30.5 1.0. 51.0 75.0 TLOW	TIME 98.5 31.0 35.8 FLOW
18:49:51 4941544 1543308 5550 51.8	11:30:49 2218728 866788 2488 58.5
PROCRAM- 10- ATA BOPAIR OUF-F? 21/87/28 SAMPLE VOL- SEL SAMPLE: 15 CONNIS/CM TIME 28.5 10.5	PROCEAN- ID- ATA DOPAIR ON 21/47/28 Sample Vol- Sel Samples- 15 counts/cm Time 28.5 31.8 55.8 Flow 11:32:48 2128548 828848 2148 58.5
POCRAM-	PROCEAN-
10= ATA BOPAIR OFF 21/47/28	10- AT& BOFAIR ON 21/87/28
SAMPLE VOL= 38L SAMPLEM- 16 COUNTS/CM	SAMPLE VOL- SAL SAMPLE® 16 COUNTS/CM
TIRE 32.5 31.8 55.8 FLOM	TIME 20.5 31.0 35.8 FLOW
18:53:49 488448 1558668 4588 51.8	11:34:47 2189808 825180 2868 58.5
PROCEAN-	PROCEAN-
13- ATA DOPAIR ON-FP 21/47/28	12- AT& DOPAIR ON 21/87/28
SAMPLE VOL- SHL SAMPLEN-17 COUNTS/CM	Sample Vol- Sel Samples-17 Counts/CM
TIME)8.5 11.6 V5.6 FLOM	Time 28.5 31.8 55.8 Flow
18:551.4 GAT244 1552745 5046 51.6	11:36:46 2827988 881468 1588 58.5
PROCEAN-	PROCRAM=
13= ATA DOPATE ON=7 21/07/20	13= ATA DOPAIR ON
SAMPLE VOL= SEL SAMPLEN= 18 COUNTS/CM	SAMPLE VOL- Sel SAMPLES - 18 COUNTS/CM
TIME >0.5 21.4 2000 159208 5300 51.0	TIME 28.5 31.8 35.8 FLOU
18:57:47 410800 1592208 5300 51.0	11:38:45 1956188 765188 2868 51.8
PROCEAN	PROCRAM-
13- ATA DOPAIR ON-FF 21/47/28	18= ATA BOPAIR ON 21/87/28
SAMPLE VOL- SEL SAMPLEN 19 COUNTS/CM	SAMPLE VOL- SEL SAMPLEN- 19 COUNTS/CH
TIME 96.5 31.8 35.8 FLOW	THE 28.5 31.0 35.6 FLOQ
18159:46 4198868 1631288 5588 51.8	11:48:44 1917528 768368 1768 58.5
PROSENT 15- ATA DOPATE OFF ^{CC} 21/87/28 28-ATE VOL: Set SAMPLES 28 COUNTS/CR 38-ATEL VOL: Set SAMPLES 28 11:81:43 427788 1558888 5328 54.5	PROCRAM= 21/87/28 18= ATA BOPAIR ON 21/87/28 SAMPLE VOL- S&L SAMPLER- 28 COUNTS/CH TIME 28.5 31.8 35.6 FLOU 11:42:43 1864928 732448 1788 58.5

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5.3. Annex B – Particle counter calibration certificate

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CONSTAT DE VERIFICATION: COMPTEUR DE PARTICULES CALIBRATION CERTIFICATE: PARTICLES COUNTER N° 2020-03-09-01

Mode opératoire : ACC-DOC-082

1. IDENTIFICATION DU MATERIEL / CALIBRATED INSTRUMENT

Type de Matériel / Designation	Compteur de Particules / Particles Counter	
Marque & modèle / Type	CLIMET CI-450t	
Numéro de Série / Serial Number	104182	
Identification	IUA-CPT-10-03	
Propriétaire / Owner	IGIENAIR MIDDLE EAST	

2. CONDITIONS AMBIANTES DE MESURE / AMBIANT CONDITIONS

21,1°C ; 989 hPa

3. MATERIEL DE REFERENCE / REFERENCE INSTRUMENT

Désignation / Designation	Identification	Date de fin de Validité / Date of issue		
Particules 0,3 μm	NANOSPHERE 303 nm Lot 189903	01/10/2020		
Particules 0,5 μm	NANOSPHERE 508 nm Lot 193188	01/01/2021		
Particules de 1,0 μm	MICROSPHERE 994 nm Lot 193291	01/01/2021		
Particules 5,0 μm	MICROSPHERE 5027 nm Lot 194633	01/02/2021		
Débitmètre / Flowmeter	IRA-DEB-16-01	08/08/2020		
Compteur de particules / Particles Counter	IRA-CPT-13-04	26/09/2020		

Remargues / Remarks:

Absence de filtre absolue dans la mallette. No absolute filter in the case.

ACC-DOC-124: Constat de vérification Compteur de particules - version du 28-02-2020

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<u>N° 2020-03-09-01</u> 4. TESTS METROLOGIQUES / METROLOGIC TESTS

Paramètre / Parameter	Valeur cible / Target value	Valeur lue / Read value (L.min-1)	Incertitude / Uncertainty (k=2)	Conformité / Results
Débit / Flow	50 ± 2,5 L.min-1	49,71	0,69	CONFORME / PASS
Taux de faux comptage / False Count Rate	≤ 3 particules sur 10 minutes / ≤ 3 particles on 10 minutes	1	/	CONFORME / PASS

Paramètre / Parameter	Valeur cible / Target value	NRef particles (total count)	Ni particles (total count)	Efficacité / Efficiency Ni/Nref	Incertitude / Uncertainty (±%)	Conformité / Results
Efficacité de comptage à 0,3 μm	100% ± 20%	56800	67941	119,6%	12,3%	CONFORME / PASS
Efficacité de comptage à 0,5 μm	100% ± 10%	32622	30719	94,2%	17,7%	CONFORME / PASS
Efficacité de comptage à 1,0 μm	100% ± 10%	42729	38579	90,3%	9,7%	CONFORME / PASS
Efficacité de comptage à 5,0 μm	100% ± 10%	3280	3534	107,7%	11,5%	CONFORME / PASS

Critères de conformité / Conformity Standards : Efficacité à / Efficiency at 0,3 μm: 80 % < Valeur / Value < 120 % Efficacité à / Efficiency at 0,5 - 1 - 5 μm: 90 % < Valeur / Value < 110 % Incertitude avec k=2 / Uncertainty with k=2

5. CONCLUSION

Date d'étalonnage / Calibration date: L'appareil est déclaré / Instrument is: Validité d'étalonnage / End of validity: Signature:

09/03/2020 CONFORME : 09/03/2021 Eloi GRAND Responsable métrologie



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