IAQ Measurement Report

Validation of ASPRA air filtration at Canisius-Wilhelmina Hospital

in Nijmegen, The Netherlands

VFA-Solutions
clean air everywhere

VFA-Solutions
The specialist in air treatment and indoor air quality

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1. Summary

1.1. Introduction

Air contaminants such as fine dust, bacteria, viruses and mold can present a significant health hazard to people as these particles may cause irritation and even disease when they are breathed in and enter into the respiratory tract. This is particularly true for the most sensitive and vulnerable group of people including immunocompromised or generally weakened persons, allergy sufferers and surgery patients. Therefore, to safeguard patient health, highest air quality standards must be respected in any medical setting but especially in intensive care.

To promote better indoor air quality in the preparation chambers of operating rooms 9+10 at Canisius-Wilhelmina Ziekenhuis (CWZ) Nijmegen, a VFA ASPRA 1000SA air purifier was installed above the suspended ceiling of the preparation chamber. With this installation it was aimed to reduce the elevated particle concentration and colony forming units in the preparation chamber. The effectiveness of the implemented measures was evaluated by methods and acceptance criteria specified in the current expert reports, guidelines and standards.

This report describes the implementation and results of the validation study. It was demonstrated that, after placing the ASPRA air cleaner, the particle concentration and the number of colony forming units in the preparation chamber satisfy the conditions stated in the current expert reports, guidelines and standards.

In addition to the above, a VFA ASPRA Mobile air cleaner was placed in the preparation chamber of operating room 1 (ophthalmology, eye surgery). The particle concentration measurements revealed 100% filtration efficiency, equal to the performance of standard HEPA filters.

1.2. Content of the validation study

The validation study consists of:

- Flow measurements at the VFA-ASPRA unit and the existing air diffusers
- Room Classification according to ISO standard 14644-1
- Air-sampling / Duplo measurements of colony forming units (CFU)
- Noise measurements
- HEPA filter validation

1.3. Summary of test results

Preparation chamber of OR-10

Description		Target	Range	No ASPRA	With ASPRA		
					Setting 3	Setting 2	Setting 1
Air circulation rate [1/h]		≥ 12	≥ 12	<5	≥ 13	7	4,9
Ventilation rate [m³/h] (external air supply minimal 50 m³/h conform to ARBO)		150	> 150	90	145	-	-
Airborne Particulate Cleanliness Class (ISO 14644-1 based on 0.5 µm)		ISO5	Not defined	ISO7	ISO5	-	ISO5/6
Microbiological air quality [CFU/m³]		0	<1	7.0	0,8	-	1
Noise emission [dB(A)] (ISO-14644-4)	Setting 1	45	< 60	-	-	-	43
	Setting 2			-	-	51	-
	Setting 3			-	56	-	-

Preparation chamber of OR-9

Description		Target	Range	No ASPRA	With ASPRA		
					Setting 3	Setting 2	Setting 1
Air circulation rate [1/h]		≥ 12	≥ 12	-	-	-	-
Ventilation rate [m³/h] (external air supply minimal 50 m³/h conform to ARBO)		150	> 150	-	-	-	-
Airborne Particulate Cleanliness Class (ISO 14644-1 based on 0.5 µm)		ISO5	Not defined	ISO6/7	-	-	-
Microbiological air quality [CFU/m³]		0	<1	10.5	-	-	-
Noise emission [dB(A)] (ISO-14644-4)	Setting 1	45	< 60	42	-	-	-
	Setting 2				-	-	-
	Setting 3				-	-	-

Preparation chamber of OR-1

Technical inspection	Acceptance criterion	Result
Lekscan HEPA filter 1 [No. particles ≥ 0.5 µm/Cuft]	0	Pass
Lekscan HEPA filter 2 [No. particles ≥ 0.5 µm/Cuft]	0	Pass
Lekscan VFA ceiling unit [No. particles ≥ 0.5 µm/Cuft]	0	Pass

1.4. Conclusions

As demonstrated by the results of this validation study, placement of an ASPRA 1000SA air cleaning unit reduced both the particle concentration and the colony forming units in the preparation chamber such that all obtained values are within the acceptance limits of the current guidelines.

It was also demonstrated that filtration efficiency of the ASPRA air cleaner was equal to the performance of standard HEPA filtration. Within the accuracy of used test equipment, filtration efficiency of the ASPRA was 100%.

2. Evaluation study

This report relates to the measurements performed on 22-09-2013 regarding the air quality evaluation in the preparation chamber of operating rooms 9 and 10 at CWZ Nijmegen. The microbiological assessment (CFU-unit determination) was performed on 17-10-2013. Also included are particle concentration measurements performed in the preparation chamber of operating room 1 on 30-04-2014.

Results of these measurements are compared to results obtained in the previous validation report (project 18595-4-2, dated 21-08-2013) and the acceptance criteria as suggested by CWZ in the draft document "Validation criteria existing operating rooms in the CWZ. (v1.0)"

3. Data evaluation

3.1. Volume flow measurements

A volume flow of 145 m^3/h was measured at the air diffuser (the air inlet towards the room). This is an improvement considering the 90 m^3/h determined during the previous periodic inspection.

The ASPRA 1000SA unit moved >400 m^3/h. The ventilation rate was determined as < 5x/h (145 m^3/h) which fails to meet the requirement of ≥ 150m ^{3}/h, if only slightly.

The air circulation rate is > 13x/h, which meets the requirement of > 12x/h. At speed setting 1, the ASPRA provides 175m ^{3}/h, which does not meet the requirement of > 12x/h.

3.2. Classification according to ISO standard 14644-1

There are no specific requirements (as defined by CWZ) regarding the ISO class in the evaluated preparation room. After placing the ASPRA air cleaner the preparation chamber meets the requirements of ISO class 5, based on particles ≥ 0.5 µm/m³. This classification is equal to the requirements for the operation zone inside the operating room. According to the previous validation report (project 18595-4-2, dated 21-08-2013), in the absence of the ASPRA air cleaner, merely ISO class 8 was obtained based on the measurement of particles ≥ 0.5 µm/m³.

Placement of the ASPRA unit reduced the airborne particle concentration by a factor of 1000 (max), resulting in ISO class 5. At ASPRA speed setting 1, the max. reduction is 100x resulting in ISO class 5/6.

3.3. Microbiological air quality

According to the "Beheersplan Luchtbehandeling Operatieafdeling" (i.e. the Management plan on air treatment in surgery departments), the CFU value determined in an unused operating room is a measure for the air quality of the supply air and thus a measure for the effectiveness of the technical installation and applied cleaning routines. A target value of <1 CFU/m³ should be achieved by a proper air treatment installation and proper cleaning.

After placement of the ASPRA, the preparation chamber of operating room 10 meets the target value of <1 CFU/m³.

3.4. Noise measurements

There is no specific limit for noise levels in preparation chambers. This is because preparation rooms are no common rooms and used temporarily only. According to ISO-14644-4:2001 F4.2 "Sound pressure level", a noise level between 55 and 65 dB(A) is commonly acceptable. According to the guidelines for operating rooms, the target value ranges between 45 and 48dB(A).

Noise measurements are performed at 2 different locations in the room, at the very least, where one measurement location must be within the active working area. At speed setting 1, the ASPRA meets the target value of 48dB(A), setting 2 and 3 comply with the limits defined by ISO-14644-4.

4. Advice

4.1. Technical adjustment

The deviation with respect to the ventilation is of technical nature and can often be corrected by adjustment of the existing HVAC system. The preparation room meets the current regulations provided that no more than two persons perform work simultaneously.

4.2. Microbiological air quality

As part of this evaluation, the preparation chamber was inspected visually. The chamber was visually clean but contained building materials that may negatively affect room classification.

From the CFU measurements it has been found that the VFA ASPRA unit provides an amply sufficient reduction with respect to the number of circulating particles, and colony forming units in the air. To further reduce the risk, we recommend that the existing ceiling tiles, which release many particles at this time, get replaced by a sanitary version.

5. Measurement Process

5.1. Volume Flow Measurements

The individual flow rates of the operating rooms were measured with a micro manometer and a Pitot tube. In the preparation chambers, air flow was measured at the air diffuser (air supply to the chmcber) by means of a balometer.

5.2. Particle Concentration Measurements

HEPA inlet filters are validated by means of a particle counter equipped with a scan probe. The scan probe is placed about 2 cm downstream of the filter. This way it is checked whether the filter medium shows leakage or is otherwise damaged, such that unfiltered air might unintentionally enter the room. The VFA ceiling unit is assessed in the same manner. The particle inlet concentration (prior to filtration) is measured 30 cm below the air inlet point. For sampling positions see Appendix 6.2.

5.3. Classification according to ISO 14644-1

The total concentration of particles ≥ 0.5 µm and ≥ 5.0 µm in the operating rooms is determined by means of a particle counter. For each measurement location there are 3 measurements of 1 minute each (3 Cuft). Of these three measurements, the average particle count is determined by the particle counter.

The probe is located at a height of 1.0 meters from the floor. All measurements are performed in an operating room at rest (no personnel, no activity, but air control as if the room was in use). For measurement positions see Appendix 6.1. For the measurements under the plenum a flushing time of 3 minutes was used.

5.4. Microbiological air quality assessment

The goal of the microbiological assessment is the determination of microbiological contamination expressed in CFU/m³ (colony forming units per cubic meter of air). Subject of the measurement is a cleaned operating room at rest (no personnel, no activities). The following routine is used:

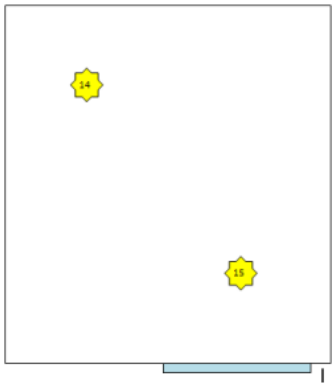
- Taking inventory of the operating rooms / visual inspection whether preparation rooms are

clean enough for relevant measurements.

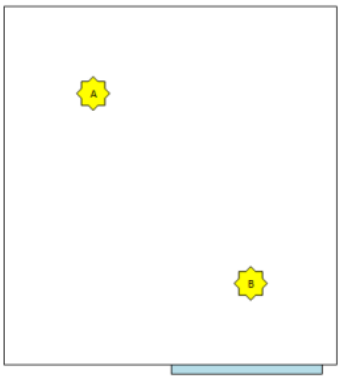
- All material and equipment such as lamps, anesthesia equipment and similar is removed from the sampling area
- Sampling locations:
  - On the OR table (3 measurements, max. available distance)
  - 4 room air samples, 0.5 m from the floor, 1 sample within 1.0 m of the air exhaust
- Sample volume: 2000 L per measurement (Duplo measurement: 1000 L per medium)
- Sampling starts with a delay of 3 min
  - Allocates sufficient time to leave the sampling area
  - Allows for a 1x refreshment of air before the measurement starts (avoiding influences from experimenter)
- Workwear: non-sterile clothing including mask and hat; activity limited to minimum
- Incubation: Sampling onto TSA (Tryptone Soya Agar) medium which is incubated aerobically for 48 hours at 30 ° C.

6. Appendix

6.1. Sampling locations OR-9 and OR-10

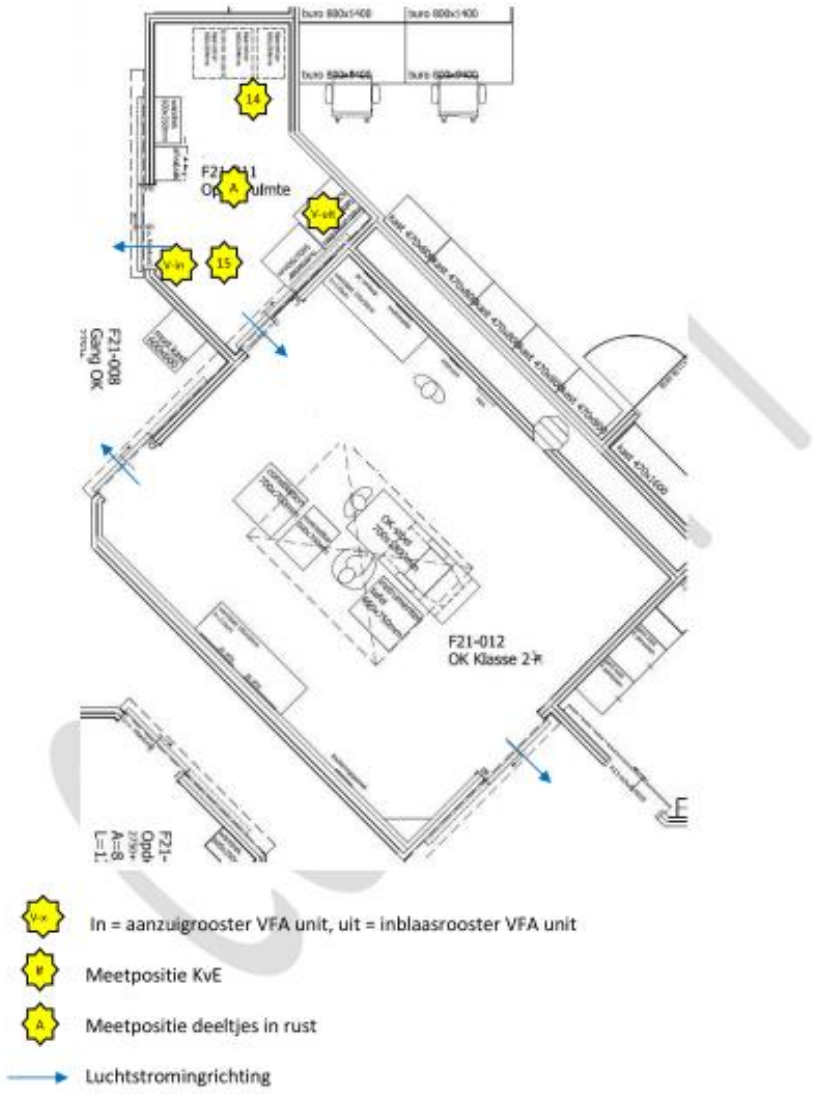


Particles, temperature, RH and noise measurements



Microbiological sampling

6.2. Sampling locations OR-1



6.3. Measurement equipment

Measurement	Manufacturer	Type	Serial-No.	Last cal.	Cal. until
Volume flow and pressure	TSI	DP Calc 8705	1030481	01-06-13	01-06-14
Volume flow	Alnor	Lowfl. 6200E	71002143	31-07-12	31-07-13
Wind speed	Testo	435	806841-90003	26-03-13	26-03-14
Particle concentration	PMS	Lasair II 310B	49096	14-05-13	14-05-14
Temperature and RH	Rotronic	HP22	60314354	01-05-13	01-08-13

6.4. Raw data OR-9 and OR-10

Project :	18595		**Datum :**	3 december 2013
Locatie :	CWZ Nijmegen	Afdeling C50	**Ruimte :**	Opdekruimte 10 en 9

Debietmetingen Opdek 10			
Meting	**Stand 3 Q (m³/h)**	**Stand 2 Q (m³/h)**	**Stand 1 Q (m³/h)**
Q inblaas	145	145	145
Q uit OK	35	35	35
Q naar gang	115	115	115
Q VFA lucht	440	260	175
Inhoud ruimte	32,4	32,4	32,4
Circulatievoud	>13	7	4,9

Statische drukverschillen OD10	
Opdek t.o.v.	**Δ p (Pa)**
OK t.o.v. opdek	7
Opdek t.o.v. Gang	15

Geluid	Stand 1	2	3
Opdek 10	43.0dB	51.0dB	56.5dB
Opdek 9	42.0dB (zonder VFA)		

Downflow snelheid en filterlektest Opdek 10							
FFU/Filter	**v1**	**v2**	**v3**	**v4**	**v gem.**	**Uitst.**	**Filterscan**
	(m/s)	**(m/s)**	**(m/s)**	**(m/s)**	**(m/s)**	**(%)**	**Pass/Failed**
1							P

Temperatuur en RV metingen Opdek 10				Deeltjes concentratie (At rest) stand 3			Stand 1	
Meetpunt	**T (° C)**	**RV (%)**	**Opdek 10**	**Meetpunt**	**≥ 0.5 µm**	**≥ 5.0 µm**	**≥ 0.5 µm**	**≥ 5.0 µm**
14	20,4	59,6		14	589	118	1471	306
15	20,6	60,4		15	800	106	1766	163
Gemidd.:	20,5	60,0	Opdek 10 Gemidd.:		695	112	1618	234
Inblaas :	19,3	63,0	**Opdek 9**	**Meetpunt**	**≥ 0.5 µm**		**≥ 5.0 µm**	
				14	2978		424	
				15	1872		234	
			Opdek 9 Gemidd.:		2425		329	

Microbiologische luchtkwaliteit meting KVE/m³		
	17-10-2013 Opdekruimte 10 bij stand 3	
Meetlocatie	A	B
Positie	L R	L R
Aantal	0 1	0 2
Gemidd.	0.8 KVE/m³	

Microbiologische luchtkwaliteit meting KVE/m³		
	21-11-2013 Opdekruimte 10 bij stand 1	
Meetlocatie	A	B
Positie	L R	L R
Aantal	1 2	1 0
Gemidd.	1 KVE/m³	

Microbiologische luchtkwaliteit meting KVE/m³		
	17-10-2013 Opdekruimte 10 bij stand 3	
Meetlocatie	A	B
Positie	L R	L R
Aantal	0 1	0 2
Gemidd.	0.8 KVE/m³	

Microbiologische luchtkwaliteit meting KVE/m³		
	21-11-2013 Opdekruimte 10 bij stand 1	
Meetlocatie	A	B
Positie	L R	L R
Aantal	1 2	1 0
Gemidd.	1 KVE/m³	

Microbiologische luchtkwaliteit meting KVE/m³		
	21-11-2013 Opdekruimte 9 zonder VFA	
Meetlocatie	A	B
Positie	L R	L R
Aantal	18 17	2 5
Gemidd.	10,5 KVE/m³	

Opmerkingen
- Technische metingen T en Rv worden niet beïnvloed door de VFA-ASPRA - Voor condities en resultaten voor de modificatie: zie validatierapportage project 18595-4-2 d.d. 21 augustus 2013

6.5. Raw data OR-1

Particle concentration at inlet (high counts)	**Particle concentration [1/m³] after ASPRA filtration (zero counts)**