Scholars Journal of Engineering and Technology (SJET) **ISSN 2321-435X (Online)**
Sch. J. Eng. Tech., 2014; 2(1):45-49 **ISSN 2347-9523 (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublisher.com

Research Article

Comparison of Hepa Filter Testing and Standard Particle Measurement in Clean Rooms

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Abstract: The high quality air without particle must be provided in operating rooms that are known as clean room. Particles cause the risk of infection in clean rooms. But, the infection risk ratio decreases by using a clean-air system. For a perfect clean room, the clean-air system must be controlled by measuring particles and must be classified in according to the international standard. The related standard is, ISO 14644-1:1999(E) Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness. In according to the standard, the clean room is classified from ISO Class 9 to Class 1 by measuring of particles (0,1µm, 0,2µm, 0,3µm, 0,5µm, 1µm, 5µm). The clean room classification requires a scientific study. But, sometimes, the particle measurement, unfortunately, is performed by non-licensed personnel by only controlling of hepa filters instead of standard methods. In this case, the clean room can not be classified. The objective of this study, is to show the difference between the scientific measurement and the random measurement of particles, and resultly, to consider the unwanted results of the hepa filter testing. In this study, the particle measurements of an operation room were performed by controlling of hepa filters and by applying international standards, respectively. Thus, the results of two measurements were compared. This study announces that the nonstandard measurements that are performed by personnel without license, may cause to report a bad operation room as a good classified room. The subject needs the standardization and the biomedical professionality.
Keywords: clean-air system, hepa filter, laminar flow, particle, clean room

INTRODUCTION

A clean room is an environment that has low level of environmental pollutants such as dust and particles. In other words, a clean room has a controlled level of particle number per cubic meter at a specified particle size.

By filtering and cleaning the air, it is possible to circulate the air of 80% without any contamination. Generally, the filters used for air filtration of clean room, are HEPA (High Efficiency Particulate Air) filters. HEPA filters remove the 99.97% of the particles (0.3µm or bigger) [1]. In clean-air systems, according to the DIN standards, the particles are removed by using the filters with 3 steps. All particles and oil-water aerosols are catched in the first filter. The second filter that is the coal filter, sucks up all oil vapor and smell. All microorganisms are filtered in third and the last bacterial filters [2].

Controlling of clean room is performed by using the method of "the clean room classification". The classification of the clean room is determined by the international standard of particle measurements. The related standard is, ISO 14644-1:1999(E) Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness [3]. The main criteria for the classification of clean rooms is particle size (0,1µm, 0,2µm, 0,3µm, 0,5µm, 1µm and 5µm) and particle concentration [4]. In addition to them, there are many technical points that must be considered during particle measurement. These are;

- number of measurement points,
- location of measurement points,
- measurement repetition,
- sample volume,
- sampling time and
- flow rate and sensitivity of the used particle counter.

In according to the ISO 14644-1 standardization, the maximum permitted concentration of particles for each considered particle size is determined from the following equation [3]:

$$C_n = 10^N \times (0,1 / D)^{2,08}$$

where

C_n is the maximum permitted concentration (particles/m^3 of air)
N is the ISO classification number, which shall not exceed a value of 9.
D is the considered particle size, in micrometers.
0,1 is a constant.

Table 1 presents selected particulate cleanliness classes and the corresponding particle concentrations (0,1µm, 0,2µm, 0,3µm, 0,5µm, 1µm and 5µm) (Table 1). In according to this standard, the mean particle concentration from each point must be equal to the limit particle concentration or lower.

Table 1: ISO Classification for clean room and clean points [3]

ISO Classification Number (N)	Maximum concentration limits (particle/m^3 : in air)					
	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	2930
ISO Class 8	--	--	--	3 520 000	832 000	29 300
ISO Class 9	--	--	--	35 200 000	8 320 000	293 000

In addition to this, the criteria that will be used to classified the cleanrooms, are given in this standard. While the clean room having laminar flow system must have ISO Class 3 conditions for 0,3 micron or larger particle size (102/ m^3), if no laminar flow, it must have ISO Class 5 (10.200/m^3) conditions. If HEPA filters are used, the efficiency must be measured for 0,5 micron and larger particle size.

The ISO classification according with particle numbers is as below:

- Stem cells unit ≤ 4 (ISO Class)
- Operating room and intensive care unit ≤ 5 (ISO Class)
- Patient room ≤ 6 (ISO Class)
- Administrative office ≤ 8 (ISO Class)

Table 2 presents the minimum required sample volume per sample location to meet ISO 14644-1. Values for each ISO class have been derived from the equation [3, 5]:

Min. Vol. (m^3) = 20 / Max. Particle Conc. Allowed

During measurement, sampling time is important to collect the minimum required sample volume. Table 3 gives the calculations for 1,0 CFM sampling rate [6].

By using nonstandard particle measurements, the true classification is not possible because all measurements are taken only from the filters and the main criteria mentioned above are not considered.

The classification of the clean room requires a scientific study. But, in nowadays, the particle measurement of the clean room, unfortunately, is performed by only controlling of filters by non-licensed persons. Thus, the clean room can not be classified [7].

By using scientific measurements, the clean room is examined as a whole room. For this application, it is important to investigate the isolation around the patient table in an operating room. The measurements are taken from several points, especially from the surface of the patient table. In this way, the performance of clean air system is controlled instead of the performance of each hepa filter.

For several years, the particle measurement in industry have been studied by many researchers to investigate the techniques of particle counting [8, 9]. In addition, in the literature, there are several studies about the comparison of the particle measurement techniques in industry [9, 10]. However, to our best knowledge, there is no study in the literature investigating the difference between the scientific measurement and random measurement in health sector.

The objective of this study, is to show the difference between the scientific measurement and the random measurement of the particles, and resultly, to consider significantly the unwanted results of random measurement.

Table 2: Minimum sample volume required per ISO Class at 1,0 CFM [6]

Minimum sample volume (m^3) required at 1,0 CFM						
ISO Class	**Certification Particle Size (µm)**					
	0,1	0,2	0,3	0,5	1,0	5,0
1	2,0	10,0	NA	NA	NA	NA
2	0,200	0,834	2,0	5,0	NA	NA
3	0,028	0,085	0,196	0,572	2,5	NA
4	0,028	0,028	0,028	0,057	0,241	NA
5	0,028	0,028	0,028	0,028	0,028	0,690
6	0,028	0,028	0,028	0,028	0,028	0,068
7	NA	NA	NA	0,028	0,028	0,028
8	NA	NA	NA	0,028	0,028	0,028
9	NA	NA	NA	0,028	0,028	0,028
ISO requires a minimum of a one minute sample, which for the standard 1,0 CFM counter is 0,0283 m^3; NA: Not available						

Table 3: ISO minimum sampling time [6]

Minutes at 1,0 CFM to Collect Minimum Sample Volume						
ISO Class	**Certification Particle Size (µm)**					
	0,1	0,2	0,3	0,5	1,0	5,0
1	70,7	353,4	NA	NA	NA	NA
2	7,1	29,5	70,7	176,7	NA	NA
3	1	3,0	6,9	20,2	88,4	NA
4	1	1	1	2,0	8,5	NA
5	1	1	1	1	1	24,4
6	1	1	1	1	1	2,4
7	NA	NA	NA	1	1	1
8	NA	NA	NA	1	1	1
9	NA	NA	NA	1	1	1
NA: Not available						

EXPERIMENTAL SECTION

In this study, the particles (0,1µm, 0,2µm, 0,3µm, 0,5µm, 1µm, 5µm and 10µm) in the operating room of Istanbul Medical Faculty in Istanbul University were measured by using a particle counter.

Firstly, the particle measurements of an operating room (25 m^2) were performed by testing of hepa filters. Secondly, it was measured in accordance with ISO 14644 and they were interpreted in accordance with the same standard. Thus, they were compared with each other.

The first measurements were taken from the mouth of the HEPA filters to test the filters. In standard measurements, the main criteria were considered. The number of measurement point was determined by examining the operation room (25 m^2). It was calculated by taking the square root of the room area (# measurement point=√25=5). Measurements were taken from the surface of the operation table and from the 4 points near the operation table. For each point, the measurements were repeated 3 times and the mean value was accepted as the measurement result. As recommended in standard, the sample volume was 28,3 liters and sampling time was 20 minutes.

From measurement results, mean, standard deviation and 95% measurement confidence were calculated. The clean rooms were classified by interpreting the results in according to the ISO 14644.

RESULTS AND DISCUSSION

The measurements performed from HEPA filters gave ideas about the performance of the HEPA filters (Table 4). At this point, neither sample volume nor measurement time was considered. According to the measurement results, each HEPA filter was classified as ISO Class 5 and it was reported that their functions were appropriate. Even if the standard table was used for classification, the classified thing was not clean room, it was only filter.

All measurement results obtained by applying standard technique, were given in Table 5. The mean and the standard deviations can be seen in the same table.

Table 4: Particle measurements of HEPA filters

	Partıcle Concentratıon (/m^3)	
Particle size	**HEPA filter #1**	**HEPA filter #2**
≥ 0,3 µm	9.298	8.905
≥ 0,5 µm	3.075	2.891
≥ 1,0 µm	704	693
≥ 5,0 µm	24	19

Table 5: Clean air particle measurements by using standard technique

POINT #1	**Partıcle Concentratıon (/m^3)**				
Particle Size	Measurement 1	Measurement 2	Measurement 3	Mean	Standard Deviation
≥ 0,3 µm	33467	36205	31993	33888,3	2137,4
≥ 0,5 µm	5605	4591	5801	5332,3	649,5
≥ 1,0 µm	2504	1917	2358	2259,7	305,6
≥ 5,0 µm	154	141	135	143,3	9,7
POINT #2					
≥ 0,3 µm	38562	36520	34932	36671,3	1819,7
≥ 0,5 µm	6850	6693	7168	6903,7	242,0
≥ 1,0 µm	2934	2762	2876	2857,3	87,5
≥ 5,0 µm	173	170	185	176,0	7,9
POINT #3					
≥ 0,3 µm	47839	45607	46599	46681,7	1118,3
≥ 0,5 µm	10014	9756	8847	9539,0	613,0
≥ 1,0 µm	3688	3776	4210	3891,3	279,5
≥ 5,0 µm	210	195	205	203,3	7,6
POINT #4					
≥ 0,3 µm	36468	34210	33867	34848,3	1413,1
≥ 0,5 µm	6245	5879	6143	6089,0	188,9
≥ 1,0 µm	2546	2348	2657	2517,0	156,5
≥ 5,0 µm	180	192	183	185,0	6,2
POINT #5					
≥ 0,3 µm	46956	44897	45999	45950,7	1030,4
≥ 0,5 µm	9886	9356	8168	9136,7	879,8
≥ 1,0 µm	2984	3272	3910	3388,7	473,9
≥ 5,0 µm	192	185	178	185,0	7,0

The particle measurements for 0,5 µm from 5 different points;

Mean = 7400 partikül/m^3
Standard deviation (s.d.) = 1859,5 /m^3
Upper Confidence Value = Mean + [$t_{0,95}$ * s.d. / $m^{0,5}$]
= 7400 + [2,1 * 1859,5 / $5^{0,5}$]
= 9146 /m^3

In according to the measurement results, because the 0,5µm particle counts and the measurement confidence were in the range of 3520 - 35200, the operation room was classified as ISO Class 6.

CONCLUSION

As a result of the measurements, the clean room was classified as ISO Class 6 and it was reported that the clean air system must be in care. But, by only checking the HEPA filters, it was classified as ISO Class 5 and it was concluded that HEPA filters work efficiently. From, Result, it is understood that the functions of HEPA filters can be efficient but it is not sufficient to clean the around of the operation table. Here, the important point is that the environment of the patient must be clean from particles.

Consequently, this study announces that the measurements which are taken from hepa filters, may specify the room that has bad conditions in real, as a better room, because of the insuffient results.

The clean room is an important parameter for health. The controls of these rooms must not be performed randomly. The subject needs the standardization and the biomedical professionality.

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