

Methods for Measurement of Hospital OR Air Quality 2018

(Note: Aerobiotix will provide particle counting free of charge – contact Nathan Utz: nu@aerobiotix.com)

1. Particle Counting (active air sampling)

- Use a particle counter (e.g. BIOTRACK <http://www.tsi.com/biotrak-real-time-viable-particle-counter-9510-bd/>) accessed April 8, 2018.
- For detection of total number of particles in the air in an unoccupied operating room and/or during a surgical case
- Should have capability to discriminate which particles are viable (microorganisms) in nature
- Laser induced fluorescence (LIF) can distinguish viable from non-viable particles
- Should provide total and viable particle counts, and have a sample collection capability
- Should be able to provide CFU (colony forming units)/m³ of air from collected sample.
- Note: European ORs use the following ISO class 5 particle count limits for unoccupied operating rooms.¹ There are no established limits for US operating rooms.

Airborne Particulate Cleanliness Classes (by cubic meter):

CLASS	Number of Particles per Cubic Meter by Micrometer Size					
	0.1 micron	0.2 micron	0.3 micron	0.5 micron	1 micron	5 microns
ISO1	10	2				
ISO2	100	24	10	4		
ISO3	1,000	237	102	35	8	
ISO4	10,000	2,370	1,020	352	83	
ISO5	100,000	23,700	10,200	3,520	832	29
ISO6	1,000,000	237,000	102,000	35,200	8,320	293
ISO7				352,000	83,200	2,930
ISO8				3,520,000	832,000	29,300
ISO9				35,200,000	8,320,000	293,000

Required Testing (ISO 14644-2)

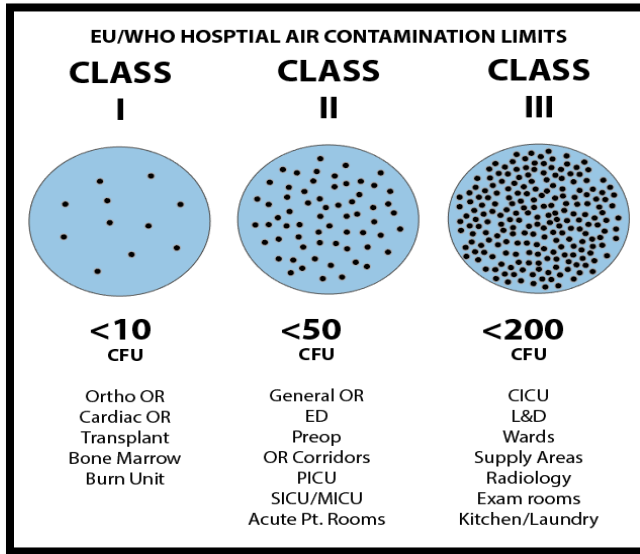
Schedule of Tests to Demonstrate Continuing Compliance			
Test Parameter	Class	Maximum Time Interval	Test Procedure
Particle Count Test	<= ISO 5	6 Months	ISO 14644-1 Annex A
	> ISO 5	12 Months	
Air Pressure Difference	All Classes	12 Months	ISO 14644-1 Annex B5
Airflow	All Classes	12 Months	ISO 14644-1 Annex B4

2. Bacterial Settle Plates (passive air sampling)

- Collected with strategically placed culture plates in an unoccupied operating room, and/or during a surgical case
- Petri dishes containing culture media, are exposed to the air for a given time in order to collect biological particles which “sediment” out and are then incubated. Results are expressed in CFU/plate/time or in CFU/m²/hour.² According to some authors, passive

sampling provides a valid risk assessment as it measures the harmful part of the airborne population which falls onto a critical surface, such as in the surgical cut or on the instruments in operating theatres.³

- The following are bacterial limits for air used in European operating rooms and other high risk environments.⁴ There are no limits established for US operating rooms.



1. ISO documents (n.d.) <https://www.terrauniversal.com/cleanrooms/iso-classification-cleanroom-standards.php> Accessed April 8, 2018.
2. Pasquarella C, Pitzurra O, Savino A J Hosp Infect. 2000 Dec; 46(4):241-56.
3. French MLV, Eitzen HE, Ritter MA, Leland DS. In: Wound Healing and Wound Infection. Hunt TK, editor. Appleton-Century Crofts, New York; 1980. Environmental control of microbial contamination in the operating room; pp. 254–261.
4. Charkowska, A. “Ensuring Cleanliness in Operating Theatres”. Int J Occup Saf Ergon. 2008;14(4):447-53.

Additional Resource:

Napoli C, Marcotrigiano V, Montagna MT. Air sampling procedures to evaluate microbial contamination: a comparison between active and passive methods in operating theatres. *BMC Public Health*. 2012; 12:594. Accessed April 8, 2018.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3444341/>