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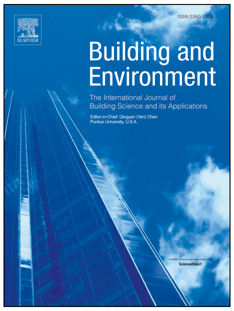

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Airborne particle and microbiological human emission rate investigation for cleanroom clothing combinations

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Abstract

The control of airborne particles and bio contaminants is a key factor in several industries in order to avoid product defects, to assure process quality and to protect personnel and outdoor environment. Cleanrooms and controlled environments are spaces with strict control of airborne contaminants and thermo-hygrometric parameters. Humans are one of the main sources of contamination in clean environments. A correct technical clothing system reduces the contamination released by humans. Despite substantial work done in this field, it is difficult to compare previous results due to differences in test rig, procedures, gowning systems and sampling locations. This study implements a dispersal chamber test methodology and an experimental campaign on 7 combinations of technical clothing and undergarments. It presents comparative experimental results of total particle and microbiological contaminants released by humans in terms of emission rate (ER). It is found that ageing factor, sterilization, physical movements, donning and warping type, and materials influence the human ER in clean environments. Sterile garment systems entirely composed of synthetic materials decrease the particle release compared to the non-sterile mixed ones. Sterile garment systems show a better performance, achieving 10 to 30 times fewer particle emission rates in wider movements and almost zero microbiological release. A low human contamination ER benefits the cleanroom design and operation, either reducing the energy consumption or increasing the number of personnel in clean environments.

Keywords: emission rate, particle and microbiological contamination; cleanroom clothing system combination; cleanroom fabric, cleanroom activities.

Highlights

- Human particle and microbiological emission rate depend on clothing systems quality and combination.
- Human activity vigor influences total particle release in clean environments
- Polyester undergarment has better barrier performance than cotton.
- Single-use sterile garments show the lowest particle and microbiological emission rates.

1. Introduction

The control of airborne particles is a key factor in several industrial sectors to avoid product defects, to ensure process quality and to protect personnel and outdoor environment [1, 2]. In some circumstances, the airborne contamination control is extended to consider biocontaminants and/or gaseous pollutants. Cleanrooms and controlled environments are spaces with a strict control of the airborne contaminants, along with temperature, humidity, and pressure of the indoor air. Standards and guidelines [3, 4, 5] provide rules to classify cleanrooms; some of them provide also indications on the design, operation and maintenance of clean environments for different processes. In aseptic condition processes (e.g. pharmaceutical productions, surgical procedures), the requirements of total airborne particulate are related to requirements of microbiological viable contaminants. In general, HEPA (High Efficiency Particulate Air) filters and a suitable air diffusion are the key elements to maintain indoor air below the required concentration limits of particles and viable biocontaminant [5, 6].

In order to pursue an effective contamination control, all sources of indoor pollutant must be assessed (people, materials, equipment, etc.). A significant amount of scientific papers investigated the human source in terms of total and viable airborne particle contamination shed from skin, clothing and breath [7, 8, 9, 10, 11]. Among all, Bhangar et al. characterized the human emission rate of biological aerosol and total particle concentrations in a common university room [12] and in a bioaerosol chamber [13, 14], varying human occupancy and activity conditions. A correlation between the human activity level and the emission of total airborne particles has been explored by You et al. [15] for 3 different types of clothing in a sealed test chamber. Licina et al. [16] in a controlled environmental chamber, focused on the emission rate of total particles shed by humans in ordinary clothing under different activity types and intensities, according to precise pre-set behaviors. Total particles dispersed can be generated by fabric friction [17] and increasing intensity of human movement [18, 13, 15]. Furthermore, fabric has been found to be an important vehicle in the collection and transfer of biological particles into the air [19, 20, 21]. Licina and Nazaroff [22] characterized the clothing release fraction of particles previously deposited onto fabrics in function of dusts loading, fabric motion type, intensity, and activity duration. The influence of garment fabrics, such as cotton, polyester, and wool, during different movements and intensities, has also been evaluated by Yoon and Brimblecombe [23] with three different experimental test methods (dancing, shaking, mixing air shower) to determine the total particle flux released by visitors in museums.

Most of the aforementioned studies focused on the human particle emission rate when clothed in civil garments in indoor environment characterized by standard HVAC systems. The air diffusion in such studies is generally quiescent or well-mixed with low airflow rate, and indoor furniture may influence particle shedding and deposition [24]. Under these terms, the human contribution may not be clearly discernible, since it may not be the predominant source of airborne contamination, as it is in cleanrooms. In controlled environments, where other sources are absent and particles in the supply air are removed by high efficiency air filters, human occupancy and activities are considered the main contributors to indoor contamination [25, 26].

Extensive scientific literature [27, 28, 29, 30, 26] highlights the link between airborne particle concentration and human occupancy within a clean environment, with particular attention to clothing such as surgical gowns for operating theater. In cleanrooms, the worn technical garments can be single-use (SU) disposable or multiple-use (i.e. reusable after proper cleaning). While both types are typically made of synthetic fabrics, they differ in terms of fabric warping and sewing, shape, and donning. The technical clothing systems can be different in terms of sterilization process, if required. In addition, reusable garments necessitate Washing and Drying (WD) or Washing, Drying, and Sterilization (WDS) cycles between uses and their performance also depends on these procedures. The adopted gowning system in clean environments usually includes also a set of gloves, head net, mask, and goggles. In highly demanding environments (e.g. pharmaceutical Grade A and B aseptic environments), personnel usually wear also inner garments, shirts, socks and trousers under the primary coverall suit system, and sterile googles. Level of personnel activity and the characteristics of gowning system strongly influence the airborne particle generation [12, 13, 10, 16, 22, 15, 31].

The particle Emission Rate (ER) generated by humans and their clothing can be calculated by applying the mass balance equation for particles [12, 16] within a dispersal chamber. The emission rate term is also called Source Strength (SS), and it can be referred to both total and biological particle contamination generated by a person gowning a precise set of clothing system under specific conditions.

The airborne particle ER generated by humans wearing cleanroom garments has been a hot topic for many years. Austin's indexes [32] sets reference values of particle concentration for different person movements, showing that particles concentration (≥ 0.3 µm) increases with activity, from 10 particles per minute (pp/min) per person standing still up to 10^3 pp/min for intense walking when a coverall membrane is worn. Xu [33] found a source strength for a person with cleanroom clothing sitting still approximately equal to 10^3 particles per minute for particles ≥ 0.5 µm.

More recently, Ramstorp et al. [34] evaluated the particle emission rate of different technical garments (cleanroom garment vs undergarments) during scheduled movements. ER results were in the range of 40×10^3 pp/min (sitting still) to 180×10^3 pp/min (walking on the spot) for particles sized ≥0.53 µm. Same results have been obtained by Hu and Shiue [35] in their empirical curve for fitting the human particle ER in function of activity and vigor. Results obtained by You et al. [15] for different clothes (smock cleanroom, polyester sportswear, and cotton suit), at different intensities of physical movements, take into account night-time exposure to external air to suppress the influence of initial particle loads, as done by Licina [16]. The study is carried out on a single reference person under defined movements.

The total and microbial particle emission rate by humans was investigated by Whyte and Hejab [25] who focused on the different particle emission rate of male and female test persons. Reusable and disposable cleanroom [36] and surgical clothing systems in a dispersal chamber [27] were characterized by Ljungqvist and Reinmuller. They observed a microbiological source strength, expressed in Colony Forming Unit per second per person (CFU/s/person), ranging from 0.7 to 5.0 for different clothing fabrics, and from 2.1 to 10.9 respectively, for disposable and reusable suits [36]. Tammelin [37, 38] focused on the emission rate of surgical scrub in real activity; while Sadrizeh [39] evaluated numerically the clothing performance in terms of microbiological human emission rate in operating theaters.

Studies on cleanroom clothing systems emission rate carried out to date used different test and measurement procedures. The position of the sampling probe in the test chamber before the exhaust duct placed at the bottom [26], or close to flow disturbances [36], or at the bottom of the vertical wall [25] under various test conditions [40, 41, 42] may not to be the best way to measure significantly the particle emission rate.

To quantify the contamination ER of humans when clothed with different combinations of technical gowning systems, this study has conducted an experimental campaign evaluating the total and viable human emission rates. In addition, to assess the influence of the type and intensity of physical activities performed, a test person undertook predefined and sequential activities within a complete unidirectional airflow test chamber [43]. Number of Washing-Drying (WD), Washing Drying and Sterilization (WDS) cycles, type of sterility process were variables used in experiments. Stationary sampling points for total and viable airborne particles were selected by studying the particle behaviors within the exhaust tray and duct of the experimental test chamber.

A further aim of this study is to enrich the scientific literature with new experimental results on human emission rate with combinations of cleanroom gowning systems, such re-usable, disposable coverall and undergarments made of cotton, synthetic or mixed fabric. To the best of our knowledge, this is the first comprehensive study offering such contribution. The results of this comparative study are potentially helpful in choosing the right garments combination to keep the contamination level as low as possible.

The correct understanding of human emission rate, as suggested by cleanroom ISO standards [30], can help to reduce the ventilation energy demand where strict contamination limits must be respected [44].

2. Methodology

We evaluated 7 technical gowning systems by combining 5 technical clothing (two disposable and 3 reusable types) and 2 undergarments. The clothing are described in detail in the Annex. The garment systems under analysis (Table 1) differ by model type, fabric, number of WD or WDS cycles, fiber density, and combination with undergarments. A total of 10 tests for each type of technical clothing system were performed by the same test person, according to the test method described below.

2.1 Experimental set-up

Experimental tests were carried out in the Body Box Laboratory of the Energy Department of Polytechnic of Milan. The clean test chamber complies with the specifications of the current standard IEST-RP-CC003.4 [45] for the testing of particle release from humans and cleanroom equipment. It consists entirely of continuous welded stainless steel and glass accurately sealed with cleanroom silicon, and is equipped with a changing room, connected by an internal door (Figure 1). Both the Body Box chamber and the changing room are 1220-1220-2440 mm (W-L-H) in size. In both rooms, there is a full vertical unidirectional airflow top-down, the air is introduced from the ceiling through a HEPA H14 filter with dimensions equal to the entire surface of the ceiling and is extracted from a floor grid made of stainless steel slats with a section of 25-25 mm (W-H). An airtight stainless steel tray underneath the Body Box floor conveys the air into an extraction duct. Body box and changing room are in ISO class 3 and ISO 4 in at-rest condition [5], respectively. Both rooms are served by two separate HVAC systems managed by a programmable logic control (PLC) system. Supply air temperature and humidity ratio are controlled through heating coils, cooling coil and vapor humidifier. A volumetric airflow rate via a variable speed fan is supplied to each chamber. A calibrated orifice plate placed before the HEPA upstream plenum of each chamber measures the airflow rate. Orifice plates are constructed according to technical standard ISO 5167-2 [46, 47]. Pressure drops across the orifices are measured by piezo-resistive transmitters.

Temperature and humidity ratio are measured at the inlet of the HEPA plenum and inside the test chamber through RTD PT100 probes coupled with relative humidity capacitive sensors. The main data of calibrated sensors are summarized in Table 2.

During the experimental tests, Body Box inlet airflow conditions have been kept constant. In particular:

Airflow rate	0.233 m^3/s ± 0.005 m^3/s, equal to 230 ± 5 Air Changes per Hour (ACH)
Temperature	20°C ± 2°C;
Relative Humidity (R.H.)	50% ± 10%;

A differential pressure of 15 Pa was kept between body box chamber and changing room. To avoid air infiltration and exfiltration, and increase the airtightness, special magnetic gaskets are placed between the glass door and the steel frame separating the two rooms. Both chambers have passed the in situ filter leakage test which takes into account damages due to filter media and to filter installation on the support frame, as well as all the environmental validation process according to ISO 14644-3 [48].

Total and viable airborne particle concentrations were measured in the exhaust duct of the dispersal chamber (Figure 1). Total airborne particle is measured by an Optical Particle Counter (OPC) (Aerotrak 9310-01, TSI Inc.). The OPC sampling flow rate is 28.3 l/min (1 CFM) with ±5% accuracy. The isokinetic sampling probe is placed in the streamline of the extracted airflow. The OPC simultaneously measures and records six channels of particle sizes (0.3-0.5 µm, 0.5-1 µm, 1.0-3 µm, 3.0-5 µm, 5-10 µm, 10-20 µm). The counting efficiency is 50% for particle diameters of 0.3 µm and 100% for particle diameters greater than ≥0.45 µm. The counter has been calibrated according to ISO 21501-4 [49] and a zero check count has been done prior to each measurement.

Microbiological airborne contamination is measured by a slit-to-agar air sampler with a d_{50} of 2.2µm (FH6, Marcus Klotz GmbH) at a sampling air flow rate of 100 l/min. The 90mm-sterile Petri Dishes used for sampling are filled with TSA (Tryptic soy agar) agar media + LTHT inactivant for isopropyl alcohol. An isokinetic sampling probe is used and placed perpendicular to the extracted airflow as shown in Figure 1 close to the OPC sampling probe.

2.2 Sampling point

The choice of the measuring point location has been made taking into account fluid-dynamic considerations of the test rig. The sampling probe is placed in the extraction duct, 6 hydraulic diameters after the last flow disturbance. The airflow regime in the duct is fully turbulent with a Reynolds number equal to $Re_{air}=4.48 \times 10^4$. The turbulent regime assures a complete and uniform particle concentration throughout the duct sampling and limits the possibility of particle deposition while increases the particle entrainment.

As reported in Figure 1, the sampling point is designed considering that large particles sized ≥10 micron must not deposit on the duct surface before achieving the sampling probe inlet. The equation of motion for a spherical particle is solved within the tray and the duct of the Body box. The following assumptions are made: (i) the effects of particles on continuous phase are negligible as they occupy a low volume fraction, (ii) the particles are sufficiently diluted so that particle interactions are negligible; (iii) particles are away from walls.

Therefore, in line with [50], the equation of motion for a spherical particle of mass *m* and diameter *d* is:

$$m\frac{d\boldsymbol{v}_p}{dt} = \frac{3\pi\mu d}{Cc}\left(\boldsymbol{v}_f - \boldsymbol{v}_p\right) + m\boldsymbol{g}$$

Where $\boldsymbol{v}_p$ is the particle velocity, $\boldsymbol{v}_f$ is the fluid velocity, $\boldsymbol{g}$ is the acceleration of gravity. These three quantities are bi-dimensional vectors. *Cc* is the calculated Cunningham correction factor equal to 1.02.

Two terms need to be considered in the equation:

- Gravity force.
- Drag force. This is proportional to the velocity difference between fluid and moving particle in a uniform viscous flow. Because the Reynolds number for the considered particle size is less than 2 and the fluid flow is thus dominated by the viscous force, the Stokes resistance law is used

The buoyancy force, which is proportional to the weight of the fluid displaced by the particle, is assumed to be negligible.

The ordinary differential equation has been solved in Matlab© by stepwise integration over discrete time steps. The following initial boundary conditions (t=0) have been considered: (i) distance between particle and sampling probe is the longest available, and (ii) particle velocity along x and y axis is considered null before interaction with airflow; (iii) air flow velocity is variable in the extraction duct, due to the variations of the duct section, and initially equal to the air velocity inside the Body Box.

The results from mathematical model confirmed that particles with dimension equal to 10 µm do not deposit onto the tray or duct surfaces before the sampling probe inlet, as they would fall onto the duct floor 65.7 m far away from the generation point. This result assures that the airborne concentration measured at the chosen sampling point is representative of the entire concentration released by the test person in the test rig, thus limiting the risk of measuring errors due to flow and geometrical disuniformity within test rig, tray and duct.

2.3 Adopted methodology

Experimental tests have been carried out to evaluate human total and viable particle emission rate when wearing seven combinations of garments systems and four activity intensities. Clothing systems tested are re-usable coverall systems made of polyester suitable for cleanroom or single use (SU) made of synthetic non-woven material. Technical characteristics of the gowning system tested are described in Table 1 (detailed information are reported in the Annex). Laundering, packaging and sterilization process of the re-usable clothing systems has been carried out by a certified professional company. Tests have been organized in order to evaluate the effect of:

- Number of WD and WDS cycles on garment;
- Sterilization cycle;
- Inner garments type;

- Fabric material and warping;
- Body movements.

Ten consecutive experimental runs, for each of the 7 combinations of technical clothing systems under evaluation, have been carried out by the same test person.

The test person is a man, 36 years old, 74 kg, 170 cm tall, with no facial hair, and in good health conditions. Before entering the test chamber, the person wears the clothing system in the changing room according to the following order and standard procedure. The test person wears respectively: hair net, mask, inner garment and socks, one pair of sterile gloves, coverall, textile hood, long boots, goggles and another pair of sterile gloves. After each step in the previous procedure, the hands or gloves are sanitized using sterile IPA (isopropyl alcohol) at 70%.

During the tests, a series of scripted activities have been performed to simulate repeatable typical work activities in aseptic cleanroom. Each test run lasted a total of 12 minutes. Scheduled physical movements were shown to the test person on an external screen with time and pace. The following time period, activity movement, and pace were adopted: standing still for 1 minute; arm movement with pace of 0.2 Hz for 3 minutes; standing still for 1 minute; knee bending with pace 0.1 Hz for 3 minutes; standing still for 1 minute, and then walking in situ at 0.2 Hz pace for 3 minutes.

Continuous particle counting is performed using an OPC with 1-minute sampling frequency. Microbiological contamination sampling is operated using one 90 mm Petri dish per test, for a total of 12 minutes sampling. All sampling plates are incubated for 48 hours at 36°C, and then left 48 hours at room temperature before counting.

The lack of air infiltration from the outdoor environment is secured by two elements: 1) the pressure difference between the test chambers and the outdoor, and 2) the magnetic gaskets at the doors which do not let airflow coming in or leaking out. The construction material quality (glass walls and polished stainless steel) and the small volume of the chamber without furniture limit endogenous particle generation and retention to nearly zero. Moreover, the chamber and its component were electrically grounded to reduce electrostatic charge and thereby minimize the particles' deposition onto the surfaces.

In the experimental tests, a vertical unidirectional airflow with a velocity of 0.16 m/s impacts over a test person. The presence and the activity of the test person can create a convective boundary layer in the surrounding of the human body, and therefore a thermal plume over the test person. The Richardson number confirms the mixed convection between the human test person and the opposing incoming airflow (vertical). The thermal plume generated may create problem of air mixing in the top part of the test chamber [51, 52]. However, the configuration of the test rig, the full supply air diffuser on the top, and the full extraction from the elevated floor create a preferential air direction (almost close to unidirectional) partly mitigating the effect of the thermal plume. Previous studies [24, 53, 54, 15] stated that the particle deposition-loss rate, k_i, in indoor environments characterized by low turbulent ventilation (or in quiescent environments) increases with high indoor air velocity and large particle diameter. However, the calculation of this parameter is not practicable in our experimental setting. This is true despite the small thermal plume generated by the convective boundary layer (CBL). The depth of the vertical CBL close to human clothing is assumed very small [52] with very little influence in the particle shedding and releasing process from clothing systems. The particle shedding velocity (perpendicular to the test person) is supposed to be higher than the CBL's air velocity. Moreover, the thermal plume and the airborne particles above the test person head are assumed diluted by the undisturbed HEPA H14 filtered airflow nearby. In this case the influence of the k_i coefficient on the total ER is very low. The dimension of the steel slats of the floating floor excludes the particle deposition by inertial impaction, as Stokes number = 0.002 for particles equal to 10 micron [55]. Furthermore, the sampling point adopted guarantees that no particles (≥10 micron) may deposit onto the extraction duct before the sampling point.

Based on these assumptions, the particle mass balance equation used in other works [12, 22, 15] for the calculation of the particle ER in a test chamber can be simplified. The only term that takes into account the reduction of particles is that related to the extracted airflow rate. Therefore, the contamination due to the test person has been evaluated using the simplified Emission Rate (ER) approach for particle size *i* [30] defined as:

$$ERi = \frac{Ci \cdot Q}{N}$$

Where ER_i is the particle or CFU emission rate [particles per second per person, pp/s/person] for the cumulated particle size *i* or [CFU/s/person], respectively; Ci is the cumulated particle or CFU concentration expressed in [pp/m^3] for the cumulated particle size *i* or [CFU/m^3]; Q is the airflow measured in [m^3/s]; and N is the number of people.

2.3.1 Quality assurance

A complete cleaning of the Body Box and changing room is carried out by a professional cleanroom person gowned with sterile cleanroom garments before each test. All the surfaces of the chambers and ducts are cleaned with sterile Grade B polyester non-linting wipes soaked with sterile IPA (70%). The test chamber is further sterilized after cleaning with sterile H_2O_2 at 6% with a contact wet period of 20 minutes before starting the drying process. The same procedure is carried out for the microbiological air sampler which is located within a horizontal hood HEPA H14 filtered air.

A zero count, for both total and viable particles at the chosen sampling point, is carried out to assure no airborne contamination in at-rest condition after cleaning, before and after each experimental test are generated or infiltrated into the test chamber. Acceptance criteria were fixed at zero total airborne particle and zero Colony Forming Units (CFUs). The microbiological contamination is checked after the incubation period. All zero count tests carried out indeed displayed zero contamination.

3. Results and discussion

The series of experimental tests have been carried out with aim of evaluating the real performance of technical clothing as a function of standard working activities, of different combination of WDS, and garment characteristics. The major results are explained in the following paragraphs. The student’s t-distribution with 95% confidence level was used to make inference on the population mean and standard deviation. Statistical analysis was performed using Matlab©.

3.1 Effect of WDS, Donning and Fabric Type

The total particle emission rate for garments A is shown in Figure 2, averaged over the entire test and the physical movements during the test period. Tests are carried out on items with the same design and fabric composition; they differ in the number of WD/WDS cycles and type of undercoats (tests "A+c" with 1 WD or 75 WD, and test "A+p/1WDS"). The three garment systems under evaluation have similar particle emission rates for small particles, in the range of 0.5-1 μm, while they diverge for larger particles.

The garments used in tests "A+c/1WD" and "A+c/75WD" underwent 1 and 75 washing and drying cycles (WD), respectively, and used short cotton underwear with similar WD. The total airborne particle emission rate measured have nearly same values in both configurations for all particle size ranges and physical activities typologies (see Table 3 and Table 4). Garments' life cycle and number of washing-drying cycles influence the emission rate [56, 31] . It has been shown that the peak emission rate is around half the life of the garment, at 30-35 WD cycles: there is a greater particle dispersion from the fabric as a result of thinning fibers (fiber linting) and a larger space between two adjacent fibers. At the beginning and end of the garment's life, the particle release is approximately equivalent.

Test "A+p/1WDS" is carried out with garment A with 1 cycle of washing, drying and beta irradiation sterilization (WDS), plus long technical polyester inner garments and goggles for aseptic work conditions. A significant decrease of almost 3 times takes place in particle release for larger particles (≥3 μm) compared to "A+c/1WD" and "A+c/75WD" tests. This is a consequence of improved barrier performance of polyester inner garments, together with the use of goggles that reduce the body surface area exposed to the airflow.

The combination of different inner garments and sterilization processes on sterile garments' emission rates has been evaluated in tests "B+p/60WDS" and "C+c/60WDS" (Figure 3). Both tests have same fabric characteristics (garment B and C, see Annex) and number of washing, drying and sterilization cycles: 60

WDS with beta irradiation for test “B+p/60WDS”, and 30 WDS with beta irradiation plus 30 WDS water vapor for “C+c/60WDS”. Minor differences between the tests are listed below:

- Donning system. In test “B+p/60WDS”, the zipper closure is along the leg and the face opening is contoured. In “C+c/60WDS”, there is a front zipper and a wide face opening. In both cases glasses for aseptic environments were used.
- Type of inner garment. A long polyester model is used in test “B+p/60WDS”, while a long cotton model is used in “C+c/60WDS”.

Those differences may affect the final particle emission rate. In “B+p/60WDS”, both the way of donning, the position of the zipper closure and the polyester long inner garment concurred to a better performance in retaining particle emission from the human body over the entire range of measured particle sizes, as shown in Figure 3. It is noted that the sterilization method could also be the reason for this result, affecting the fiber and pore size. This parameter should be further investigated in the future.

Re-usable aseptic technical clothing systems have also been compared with disposable ones. Tests “D+p/SU” and “E+p/SU” were conducted on two sterile disposable (single-use) dressing systems together with long polyester inner garments. The garments in both cases showed a front zip closure. Sterile goggles were used in all tests. Figure 4 shows a comparison of the particle emission rate obtained in “B+p/60WDS”, “D+p/SU”, and “E+p/SU”.

Results, averaged over the entire test period, showed that for cumulated particles sized ≥3 µm, the particle emission rate of the 3 garments under tests had similar behavior, even though for smaller particles, test “D+p/SU” showed better performance.

3.2 Microbiological emission rate

Microbiological emission rate (MER) for the different clothing systems has been investigated. Averaged MER for the experimental tests performed are shown in Figure 5. Among the non-sterile multiple-use garments, e.g. Tests “A+c/1WD” and “A+c/75WD”, the number of WD cycles appears to be a critical factor for MER. The gowning systems released 1.3 and 2.3 colony forming unit per person per second (CFU/ pp/s) for “A+c/1WD” and “A+c/75WD”, respectively.

The microbiological emission rate decreases from non-sterile to sterile clothing, with the average value dropping from 1.8 CFU/pp/s (average for tests “A+c/1WD” and “A+c/75WD”, without sterilization) to 0.1 CFU/pp/s (average for tests with sterilization cycles, tests “A+p/1WDS”, ”B+p/60WDS”, “C+c/60WDS”, “D+p/SU”, “E+p/SU”). Among sterile garments, re-usable ones (“A+p/1WDS”, “B+p/60WDS” and “C+c/60WDS”) obtained a slightly higher microbiological concentration than sterile single use (SU) clothing systems: 0.1 CFU/pp/s (average on “A+p/1WDS”, “B+p/60WDS” and “C+c/60WDS”) for re-usable compared to zero for SU systems (average on “D+p/SU” and “E+p/SU”).

Disposable garments have a better barrier performance in microbiological measurements than re-usable garments. Both the microbiological and total particle source are the lowest with the sterile disposable garment used in test “D+p/SU”. Good performance is associated with sterile single-use and reusable garments (tests “E+p/SU”, “B+p/60WDS” and “C+p/60WDS”). This is due to both the additional sterilization cycle (in reusable garments) and the use of polyester inner garments. Since 83% of the micro-carrying particles in the air have size ≥5 μm [25], polyester inner garments provides better barrier performance, because release fewer particles even for fiber friction.

3.3 Effect of movement type on particle emission rate

Four types of movements performed by the test person in the body box chamber were taken into consideration: arm movement, knee bending, walking on site, and standing still.Body movements performed by cleanroom personnel were analyzed to assess the specific particle emission rate.

The results on the average particle emission rate for all garments are confirmed once the emission rates are calculated for each movement (Table 3 and 4). The effect of the donning method and quality of inner garment influence the emission rate results. The use of synthetic inner garments, coupled with sterile garments and goggles, drastically reduced the total particle and microbiological release from the human body.

The large movements performed within the test chamber (arm movement and knee bending) significantly increase the release of particles. High vigor activities are associated with increased air circulation in the space between the body and the suit, resulting in a higher airflow rate facing outward from the openings in the gowning systems, in particular from the large face opening. It is observed that the garment used in test “C+c/60WDS”, which has a large opening around the face and neck, increases the particle release in all the movements performed for both cumulated particle sized ≥0.5 µm and ≥5 µm. Disposable garments (tests “D+p/SU” and “E+p/SU”) have very low particle emission rate in all movement simulations with respect to the re-usable ones, with the exception of test “B+p/60WDS” where the use of polyester long inner garments increase the filtration performance of the gowning systems.

In clean environments, gowned personnel move with low energy intensity to keep the contamination release as low as possible. In the test chamber, given the limited available space, the walking-on-the-spot activity resembles standing still with minimal leg movements, as shown by the experimental values (Tables 3 and 4). The knee bending and arm movement stages reached high particle emission rate, although the simulated activities were fast and uncommon relative to the ordinary routine.

Regarding the standing still sampling, it is important to highlight that the test person returns to the standing still position after completing the scripted activities.

4. Limitations

Human physiological characteristics (age, gender, race, activities) and environmental conditions (air velocity, temperature and relative humidity) may set limitations of this experimental study.

The measurement method relies on the assumption that the thermal plume generated by the convective boundary layer of the test person has small influence on the particle concentration distribution and on the airflow. Further analysis and techniques different from the particle concentration decay method should be envisaged in order to assess how much particle deposition loss rate could affect. Such investigations should try to highlight the influence of different particle size and air velocity on the particle deposition loss-rate in high ACH and not turbulent environments.

The individual characteristics of the test person employed in this study may limit the generality of our findings, even though it allows to make comparisons between the gowning systems tested. For example, gender, age and race, may affect the final particle emission rates. People with high metabolic rates tends to have high particle emission rate, as well as males tend to emit more than females.

In addition, the washing-drying-sterilization method of clothing may affect the particles emission. In this study, the WDS cycles were all processed by a professional cleanroom laundry. This is a parameter to be deeper investigated and optimized in future researches.

Another limitation of our study is given by the performed activities which are ruled by standard procedures but slightly different from the real activities commonly conducted in real cleanroom production environments. On site investigations to measure the particle emission rate from humans gowning technical clothing combinations are necessary for a better characterization of the phenomenon.

5. Conclusions

The combination of technical clothing systems is a key issue in assessing the total and viable airborne particle emission rate released by humans under different physical and occupational activities in clean environments.

A set of cleanroom clothing systems has been experimentally tested under different combination of WD and WDS cycles, garment details and fabric characteristics. To the best of our knowledge, this is the first work addressing a complete quantification of the human particle ER for different gowning combinations and physical activities in a clean test chamber. The number of WD and WDS influence the final particle emission rate: the peak of total and viable particle release is at half-life, about 30-35 WD/WDS cycles. Reusable clothing systems have shown higher particle emission rate than disposable ones during scripted movements. Among the combination of clothing systems, polyester long-sleeved shirts and trousers performs better than cotton inner garments. The donning type and the face opening of the external coverall may change the final emission rate for both total and microbiological contamination. Goggles provide protection and an additional locking system for the suit, preventing contamination release from the face area. Human activities and vigor have a strong influence on the particle emission rate. Values associated to knee bending were up to 7.8 times higher than those for the standing still position for particles ≥ 0.5 µm and up to 7.9 times for particles ≥ 5 µm.

Although the particle and microbiological emission rate from humans also depend on other factors, the results obtained in this work can be used as baseline values for human contamination in clean environments. A lower human particle emission value can reduce the airflow associated to contamination control within clean environments, and consequently reduce the energy consumption for ventilation purpose, or allow more personnel to be present.

6. Acknowledgments

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7. Bibliography

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ANNEX

Technical Clothing system description

Label	Garment type	Fabric			Disposable
		Composition	Mass	Particle filtration efficiency	
Garment A	Coverall in a single piece. Front closure with zip for the body and buttons for the hood. Boots with back zip closure.	99% polyester 1% antistatic Armor: Twill Boot covers: sole 100% antistatic SBR	180 ± 5% g/m^2	63% (≥ 0.3 µm) 66% (≥ 0.5 µm)	No
Garment B	Coverall in a single piece, with long zip closure on the inside leg. Hood with elastic opening. Boots with back zip closure.	99% polyester 1% antistatic Armor: Twill Boot covers: sole 100% antistatic SBR	102 ± 5% g/m^2	82% (≥ 0.3 µm) 86% (≥ 0.5 µm)	No
Garment C	Coverall with collar, with a long front zip. Eyes-only hood. Boots with back zip closure.	99% polyester 1% antistatic Armor: Twill Boot covers: sole 100% antistatic SBR	102 ± 5% g/m^2	82% (≥ 0.3 µm) 86% (≥ 0.5 µm)	No

Garment D	Coverall in single piece with front zip closure. Integrated hood and mask with grasp ties across chest. Boot covers with grasp ties and elastic opening.	Non-woven polyester. Boot covers: vinyl sole	-	94% (≥ 0.5 µm)	yes
Garment E	Coverall with collar features a front zip with protective flap, elasticated back, cuffs and ankles, and thumb loops. Hood with elasticated face-opening. Overboots feature a slip-resistant sole and tie fastenings.	Spun bonded non woven PP laminated with a film of PE. Antistatic	-	-	yes
Polyester (p) underclothes	Long sleeve sweater with cuffs; long pants with cuffs.	99% polyester 1% antistatic	95 ± 5% g/m^2	65% (≥ 0.3 µm) 72% (≥ 0.5 µm)	no
Cotton (c) underclothes	Long sleeve sweater with cuffs; long pants with cuffs.	100% cotton	-	-	no

List of Tables

Table 1 – Description of Garment system combinations

Test label	Garment type	Underclothes	Number of WD-WDS cycles	Sterility
A+c/1WD	A	cotton (c) t-shirt and shorts	1 WD	no
A+c/75WD	A	cotton (c) t-shirt and shorts	75 WD	no
A+p/1WDS	A	polyester (p) long sleeve shirt and trousers	1 WDS	Beta Irradiated
B+p/60WDS	B	polyester (p) long sleeve shirt and trousers	60 WDS	Beta Irradiated
C+c/60WDS	C	cotton (c) long sleeve shirt and trousers	60 WDS	30 WDS Beta irradiated + 30 WDS water vapor steam
D+p/SU	D	polyester (p) long sleeve shirt and trousers	Disposable (SU)	Gamma irradiated
E+p/SU	E	polyester (p) long sleeve shirt and trousers	Disposable (SU)	Beta Irradiated

Table 2 – Sensors main data

Abbreviation	Type of sensors	Accuracy at T=20°C
T	PT 100 Class A	±0.2°C
RH	Capacitive	±2% (between 0 and 90%)
P	Piezoresistive	±0.5% of reading ±1 Pa

Table 3 – Results – Cumulated particle emission rates: average (and standard deviation) at particle size ≥0.5 µm

Test	Arm movement Emission Rate [pp/s/person]	Knee bending Emission Rate [pp/s/person]	Walking still with minimized movements Emission Rate [pp/s/person]	Stay still Emission Rate [pp/s/person]
A+c/1WD	638 (477)	2922 (1074)	709 (320)	456 (312)
A+c/75WD	1200 (248)	3122 (1082)	828 (516)	488 (136)
A+p/1WDS	1402 (306)	2326 (519)	849 (236)	478 (142)
B+p/60WDS	330 (115)	446 (235)	174 (72)	184 (88)
C+c/60WDS	1106 (537)	5036 (2198)	510 (217)	595 (302)
D+p/SU	120 (46)	168 (58)	72 (23)	47 (15)
E+p/SU	504 (264)	386 (252)	127 (76)	156 (87)

Table 4 – Results – Cumulated particle emission rates: average (and standard deviation) at particle size ≥5 µm

Test	Arm movement Emission Rate [pp/s/person]	Knee bending Emission Rate [pp/ s/person]	Walking still with minimized movements Emission Rate [pp/ s/person]	Stay still Emission Rate [pp/ s/person]
A+c/1WD	80 (93)	302 (86)	45 (20)	37 (44)
A+c/75WD	63 (22)	211 (78)	52 (47)	30 (14)
A+p/1WDS	17 (12)	60 (28)	16 (7)	10 (8)
B+p/60WDS	3 (3)	9 (9)	2 (1)	1 (2)
C+c/60WDS	14 (8)	76 (42)	12 (7)	9 (9)
D+p/SU	8 (3)	8 (4)	5 (5)	2 (2)
E+p/SU	6 (6)	6 (4)	3 (3)	2 (4)

ANNEX

Technical Clothing description

Label	Garment type	Fabric			Disposable
		Composition	Mass	Particle filtration efficiency	
Garment A	Coverall in a single piece. Front closure with zip for the body and buttons for the hood. Boots with back zip closure.	99% polyester 1% antistatic Armor: Twill Boot covers: sole 100% antistatic SBR	180 ± 5% g/m^2	63% (≥ 0.3 µm) 66% (≥ 0.5 µm)	No
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Polyester (p) underclothes	Long sleeve sweater with cuffs; long pants with cuffs.	99% polyester 1% antistatic	95 ± 5% g/m^2	65% (≥ 0.3 µm) 72% (≥ 0.5 µm)	no
Cotton (c) underclothes	Long sleeve sweater with cuffs; long pants with	100% cotton	-	-	no

	cuffs.				

List of Figures

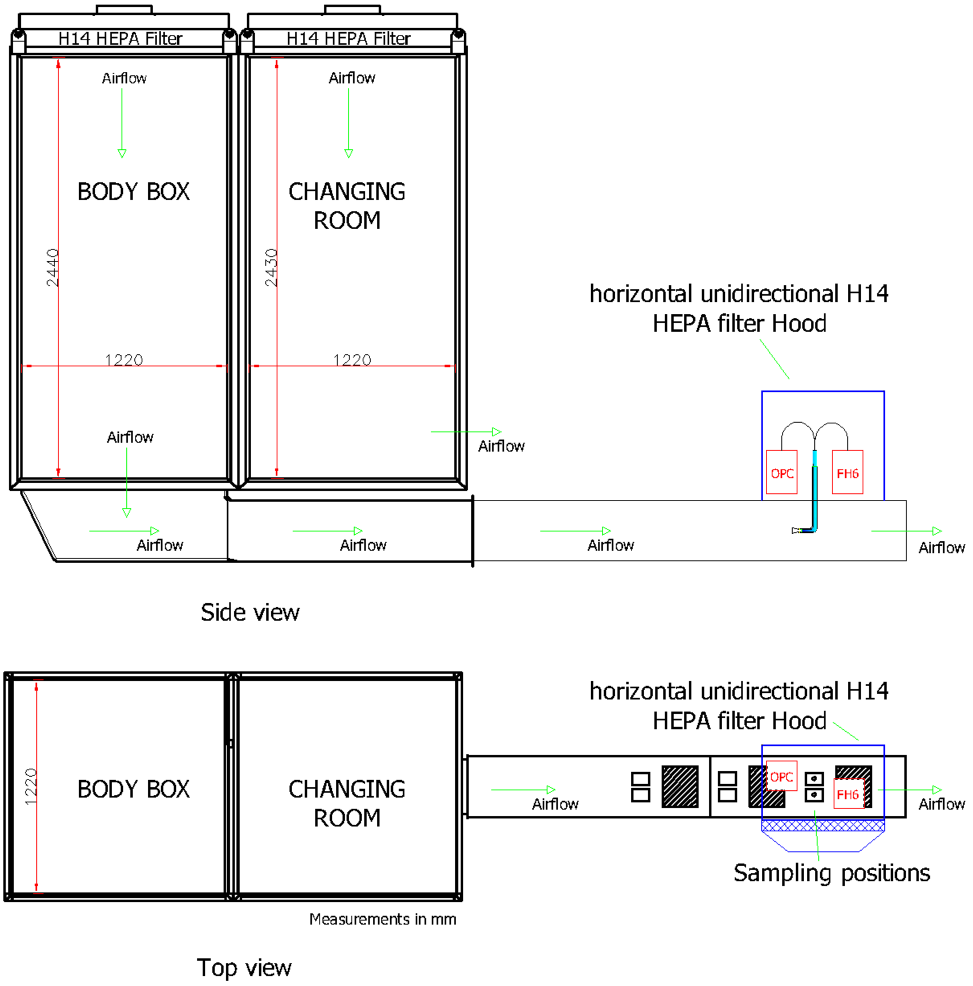

Figure 1 – Scheme and layout of the experimental test rig.

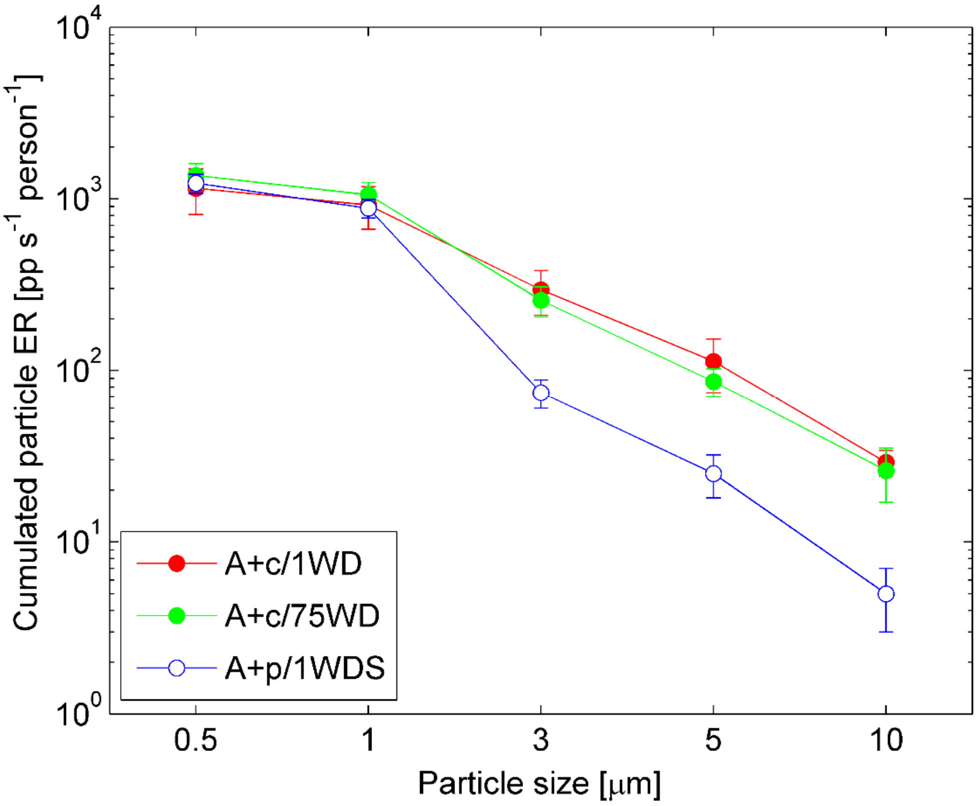

Figure 2: Cumulated particle emission rates for tests “A+c/1WD”, “A+c/75WD”, and “A+p/1WDS” as a function of particle size in µm. Data averaged over the entire test period and movements.

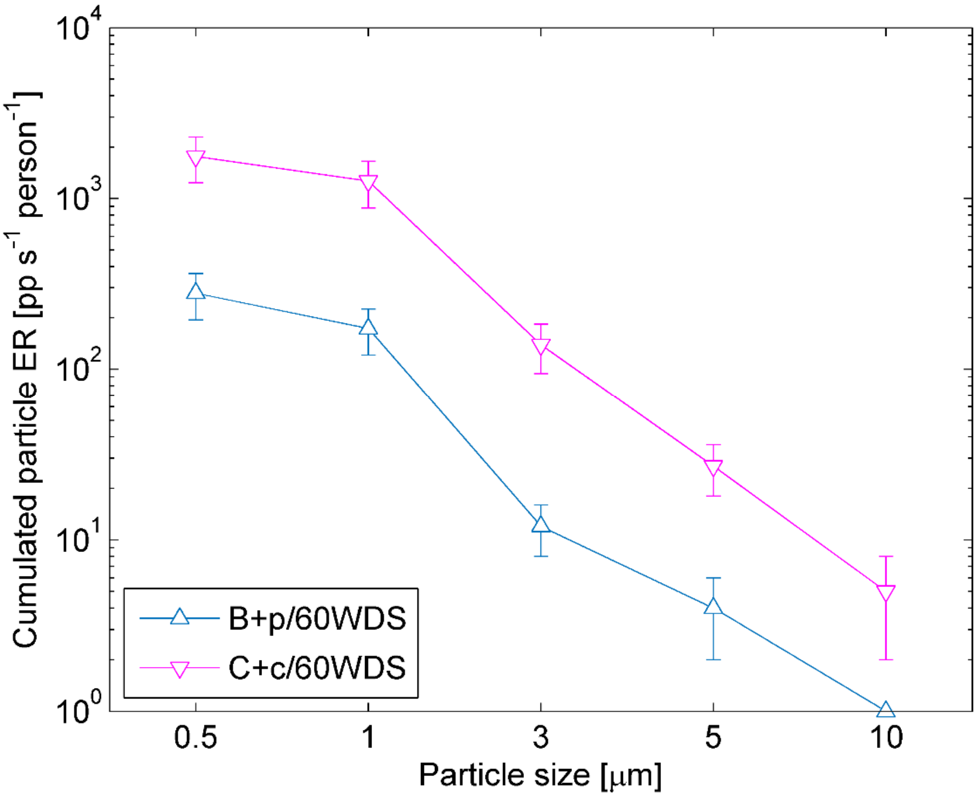

Figure 3: Cumulated particle emission rates for tests “B+p/60WDS” and “C+c/60WDS” as a function of particle size in μm. Data averaged over the entire test period and movements.

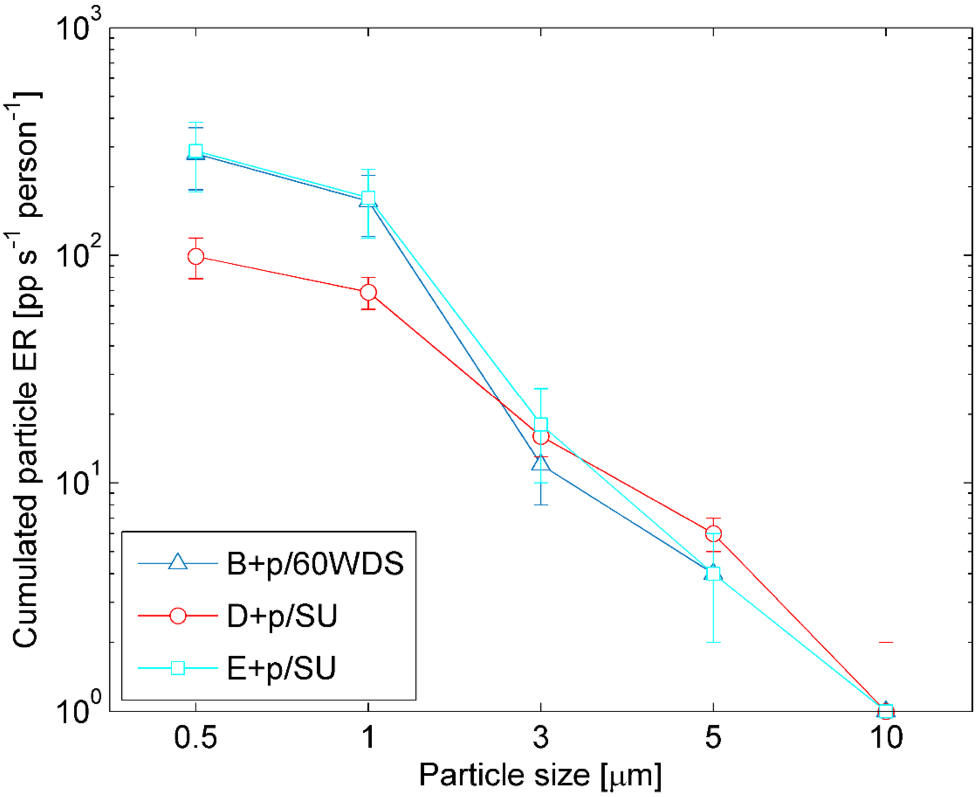

Figure 4: Cumulated particle emission rates for tests “B+p/60WDS”, “D+p/SU”, and “E+p/SU” as a function of particle size in μm. Data averaged over the entire test period and movements.

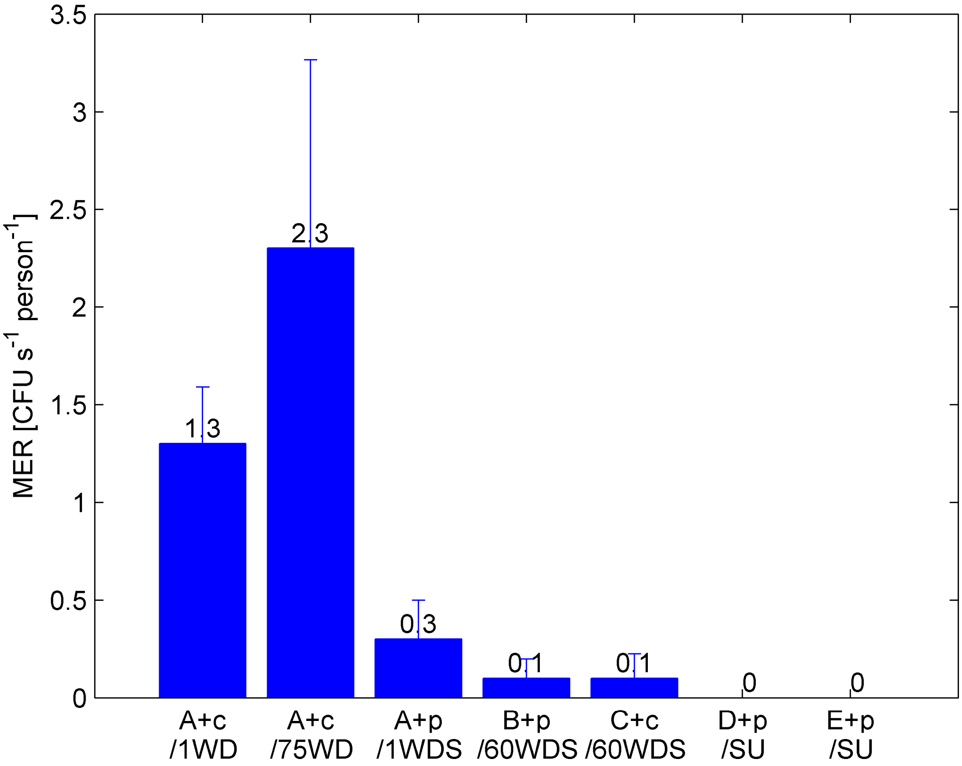

Figure 5 – Average microbiological emission rates for garments systems.

Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: