Validation and application of the personnel factor for the garment used in cleanrooms

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ARTICLE INFO

Article history:
Received 7 December 2015
Accepted 9 December 2015
Available online 2 January 2016

ABSTRACT

The cleanroom environment has many potential sources of contamination, including: operators, equipment, structures, and any surface that can create particles via friction, heat, exhaust, outgassing, and static electricity charge. Operatives working in the cleanroom are the major source of particles. While cleanroom operators work, they emit millions of particles from every activity. Particles migrate up the cleanroom garment to the head and drop to the legs during cleanroom movements. Specialized textile fabrics have been used in cleanroom garments for many years. The need for this type of fabric has increased mainly due to the need to protect critical operations in cleanrooms as well as creating comfort for operators and other personnel. This study covers the general static wind-driven method, the Helmke Drum method and the dispersal chamber to measure particle penetration, shedding, and generation, in regards to the filtration efficiency of cleanroom fabrics and garments. Firstly, particle penetration is shown to increase with increasing face velocity and decreasing particle size below 1 μm. Secondly, that a recommended upper particle-size limit should be 5 μm. Using the Helmke drum test, the size distribution of particles released from the garment is shown to follow a power law distribution, with a slope of less than 1. Furthermore, the study introduces dynamic body box for testing fabrics as well as cleanroom garments. It is more practical and sensitive when compared to traditional methods and is based on a more concise technical approach. The life-time cycle performance of a typical
cleanroom garment coverall is examined, particularly looking at the implications of pre-use sterilization. © 2016 Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

## Specifications Table

| Subject area | More specifc subject area | Type of data | How data was acquired | Data format | Experimental factors | Experimental features | Data source location | Data accessibility |
|--------------|---------------------------|--------------|-----------------------|-------------|----------------------|----------------------|---------------------|-------------------|
| Physics      | Pharmaceutical/Biotech Cleanroom | Table: 5, figure: 8 | MetOne 237B and MetOne 2100 particle counter | Raw data | Brief description of any pretreatment of samples | Particle Penetration Test, Particle Shedding Test-Helmke Drum Tumble Test, Dispersal Chamber Test | Air System Enterprise Co., LTD. Taiwan, ROC. | Correlation coefficients of particle concentration data detection is over 0.9258 |

## Value of the data

- The increasing cleanliness demands regarding the performance of modern cleanroom clothing systems.
- Particle penetration increases with increasing face velocity and decreases particle size below 1 μm.
- The size distribution of particles released to follow a power law distribution with a slope of less than 1.
- Body box for testing the efficiency of the cleanroom garments is more practical and sensitive.

## 1. Data

1.1. **Experimental design, materials and methods**

1.1.1. **Materials**

The garment tested in this study is 98% polyester filament yarn + 2% conductive yarn. The characteristics of the garment are listed in Table 1.

1.1.2. **Particle penetration test**

The apparatus was set up in a Class-10 modular cleanroom utilizing the ambient aerosol as the encounter. The test fabric was installed in a filter container which had a 25-cm (10-in.) diameter dynamic filtration area. A vacuum pump was utilized to set flow via the fabric at a rate that yielded a pressure drop of 9.5 mm H₂O. The aerosol particle counter was utilized to successively get ten 1-min upstream and ten 1-min downstream samples. From the particle counter data (MetOne 237B: ± 10% accuracy, 0.3 μm (237B) at 0.1 CFM (2.83 LPM) flow rate, linked to a manifold with multichannel; Table 2), the filtration efficiency of the media was calculated for two size ranges: 0.1 μm and > 5 μm. The test was replicated, and a second set of filtration efficiency values were calculated. If the efficacy values from the two sets were not in 15%, the test would be replicated until two values reach the goal.
to be within 15%. The average of the two efficacy values was then calculated and noted. The arrangement is shown schematically in Fig. 1.

The particles flow through the garment, if the upstream concentration of particles is \( C_u \) and the downstream concentration of particles is \( C_d \), the penetration of particles is determined as:

\[
P = \frac{C_d}{C_u}
\]

### 1.1.3. Particle Shedding Test–Helmke Drum Tumble Test

The apparatus was set up in a Class-10 modular cleanroom. The end of the sampling tube for an airborne particle monitor was mounted to pull the air from the inside of the rotating drum. The number of airborne particles was determined utilizing a particle counter (MetOne 237B: Table 2). The arrangement is shown schematically in Fig. 2.

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**Table 1**
The characteristics of the garment.

| Composition                        |
|-----------------------------------|
| 98% Polyester filament yarn + 2% conductive yarn |

| Weave                |
|----------------------|
| 2/2 twill, mm Grid   |

| Density             |
|---------------------|
| Warp                |
| 188 ends/in. (75 ends/cm) ± 5% |
| Weft                |
| 114 ends/in. (44 ends/cm) ± 5% |

| Weight                 |
|------------------------|
| g/m²                   |
| Warp   |
| 109 ± 5%               |
| Weft   |
| Polyester 75D/72F+ Conductive Yarn |

| Yarn type              |
|------------------------|
| Warp                  |
| Polyester 75D/72F+ Conductive Yarn |
| Weft                  |
| Polyester 75D/72F+ Conductive Yarn |

| Air Permeability cc/cm²/s |
|---------------------------|
| 4.93                      |

| Surface Resistivity 10⁵-⁶ ohm/square |
|-------------------------------------|
| (42% R.H., 21 °C)                   |
| DIN 54345                           |

| Friction Charges |
|------------------|
| Warp |
| 43 V |
| Weft |
| 22 V |

| Decay Time ± 0.01(42% R.H., 21 °C) |
|------------------------------------|
| Half Life s                         |
| Warp                               |
| 1 s                                |
| Weft                               |
| 1 s                                |

| Tensile Strength |
|------------------|
| Warp |
| 100.0 kg |
| Weft |
| 66.3 kg |

| Tear Strength |
|----------------|
| Warp |
| 2807 g |
| Weft |
| 1917 g |

| Wash Shrinkage |
|----------------|
| Warp |
| – 1.20% |

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**Table 2**
Specification of MetOne 237B particle counter.

| Title                  | Values                                      |
|------------------------|---------------------------------------------|
| Size Channels          | 0.3, 0.5, 7.0, 1.0, 2.0, 5.0 μm             |
| Flow Rate              | 0.1 cfm                                     |
| Sample Time            | 1 s to 24 h                                 |
| Hold Time              | 1 s to 24 h                                 |
| Location Labels        | 250 appear on printout                      |
| Datalogging            | 500 samples, rotating buffer                |
| Output                 | Built-in printer, RS-232 port               |
| Power                  | Rechargeable Ni–Cd battery, 4 h operation with printer, 8 h without or AC operation with adapter/charger |

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Fig. 1. Schematic diagram of particle penetration test apparatus.

Fig. 2. Schematic diagram of Helmke Drum test method.
A power law distribution is given by the following equation [13]:

\[ N(d) = A d^{(-B)} \]  

where: \( N(d) \) is the cumulative concentration as a function of particle diameter, \( d \) is the particle diameter, and \( A \) and \( B \) are statistically-determined coefficients.

1.1.4. Dispersal Chamber Test

A specially designed dispersal chamber (120 cm(L) \times 120 cm(W) \times 310 cm(H)) with HEPA-filtered air supply and separate make-up air unit has been deemed suitable for the evaluation of clean room clothing systems. The apparatus was set up in a Class-1 modular cleanroom. The arrangement is shown schematically in Fig. 3. The vertical unidirectional air velocity was adjusted at 0.35 m/s and the dispersal chamber is pressurized relative to the adjacent area. Room temperature and relative humidity are not controlled since the indoor environment was reasonably stable, with 23 \( \pm \) 3 °C and 25–55% RH during the tests. The total number of airborne particles was determined using a particle counter (MetOne 2100: \( \pm \) 10% accuracy, 1.7 m\(^3\)/h sampling airflow rate, linked to a manifold with multichannel; Table 3) and particles were gathered primarily utilizing a slit-sampler (brand name FH3). In some cases, they were additionally measured utilizing a sieve-sampler (Andersen 6-stage Sampler).

1.1.5. The test person: female, 58 kg, 160 cm tall, with long black hair

Cleanroom garment: A coverall and hood (100% polyester), single use facial protection and latex gloves. The coverall and hood were produced in a cleanroom environment which were new and had been subjected to washing prior to use.
1.1.6. Movement

Standing while performing arm movements: One arm at a time was moved at an angle of 90°, back and forth in a sweeping motion. The original position of the arm was directed straightly ahead with a 90° bend at the elbow. The movement frequency was one second for one arm to move back and forth.

Standing with cross beat: Both hands beat the chest from side to side, as far as possible in each direction. The time for turning from one side to the other was one second.

Standing with rotating torso: Both hands grabbing the waist and rotating the upper body from side to side, as far as possible in each direction. The time for turning from one side to the other was one second.

1.1.7. Walking on the spot: walking on the spot at a rate of two steps per second

If the contamination sources and the design of the dispersal chamber system are known, a mathematical model can be constructed of the level of airborne contaminants in a dispersal chamber having fully turbulent mixing air. The assumptions is no leakage into the dispersal chamber and an approach to 100% efficiency from HEPA filters, the simplest possible expression defining the concentration \( c \) in the dispersal chamber is as following given by Ljungqvist B and Reinmüller [26–28]:

\[
c = \frac{q_s}{Q}
\]

where \( q_s \) is source strength of outward particle flow (numbers/s), and \( Q \) is the total airflow (m³/s).

2. [(NO) Conclusions/Summary]

Validation and application of the personnel factor for the anti-static electric garment used in cleanrooms.

Acknowledgments

The authors would like to acknowledge the financial supports from Mr. Han Yang Liu and Mr. Rong Ben Chiu of Air System Enterprise Co., LTD., and Ministry of Economic Affair with Contract

Table 3

| Specification of MetOne 2100 particle counter. |
|-----------------------------------------------|
| MODEL                                         |
| 2100                                          |
| Smallest Size, \( \mu \)m                      |
| 0.1                                           |
| Number of Channels                            |
| 6                                             |
| Flow Rate, cfm                                |
| 1                                             |
| Flow Rate, L/min                              |
| 28.3                                          |
| Laser Type                                    |
| 4-port HeNe                                   |
| Communication Support                         |
| RS-232                                        |
| Optional                                      |
| Environmental Probes                          |
| Air Velocity special:dP                       |
| Coincidence Loss 5%                           |
| (counts/ft³)                                  |
| 40,000                                        |
| Display Type/Digits                           |
| Red LED                                       |
| Memory Buffer Records                         |
| 400                                           |
| Location Labels                               |
| 1000                                          |
| Printer Support                               |
| Built-in or External                          |
| Vacuum Source                                 |
| AC; Oscillating                               |
| Size, \( W \times H \times D \), in.          |
| 13.5 \times 7.0 \times 22                     |
| Size, \( W \times H \times D \), cm           |
| 34 \times 18 \times 57                        |
| Weight, lbs/kg                                |
| 42 lbs (19 kg)                                |
| Accessories Included                          |
| Isokinetic Probe w/ Tripod Zero Count Filter  |
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