Signs of ageing of sterile cleanroom garments

dastex REINRAUMZUBEHÖR

How often can cleanroom garments be decontaminated and autoclaved?

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As is well known, humans are amongst the biggest sources of contamination in clean environments – regardless of whether these are merely particulate monitored areas or microbiologically controlled zones. The fact that cleanroom garments thus has a decisive protective function in protecting clean processes from the corresponding contamination caused by humans and their personal garments was already proven in a major study in 2002, which was carried out in a so-called Body-Box.

The study at that time dealt with the question of how many particles an employee emits per minute depending on the garments worn and the movement performed. The results are summarised in Table 1. The subsequent question from a microbiological point of view, „Can these values also be used to draw conclusions about possible germ counts?" could not yet be answered or substantiated with data at that time.

There are some publications on the subject which theoretically deduce a connection, but a study with measurement results similar to those of particle emission measurements (see above) has not been carried out to date. Dastex has dedicated itself to this task and has carried out a corresponding study in 2015, again using the so-called Body-Box method. The data are summarised in Table 2. It could be shown that an increased number of microbial, viable contaminations were also recorded with persons who emitted a large number of particles. A direct correlation, however, could not be demonstrated.

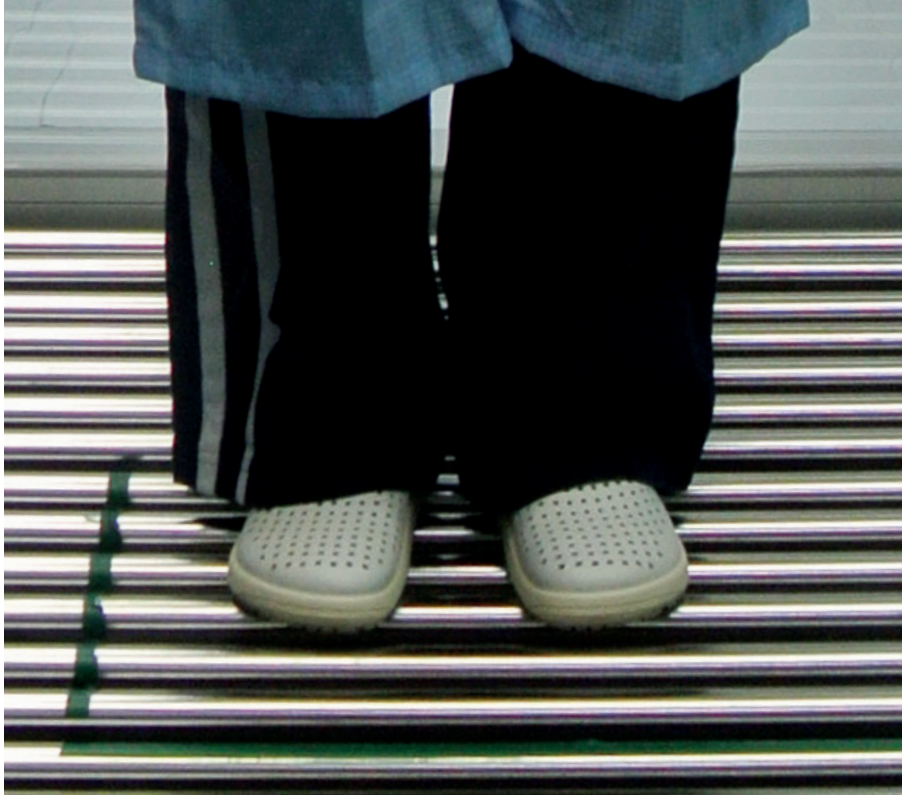

Fig. 1: Body-Box air exhaust duct

Fig. 2: Test person simulating walking movement in the Body-Box

The metrological basis for the 2015 study and also for the new study presented here was the use of a relatively new measuring instrument from TSI Inc.: the BIOTRAK® 9510-BD. With the help of this real-time viable particle counter, it is now possible to quantitatively detect airborne microbes and, if necessary, to analyse the collected airborne microbes. The operation of the counter is shown opposite Info box „Measuring method" described in more detail. A special feature of the BIOTRAK® is that not only airborne germs can be quantitatively detected, but also airborne particulate contamination at the same time. Thus, it is possible to differentiate between viable and non-viable particles.

The study presented here deals with the detection of airborne particles and microbial contamination emitted by persons in defined cleanroom garments in relation to the degree of ageing of the garments. The defined garments were tested in the condition „new" – after a one-time decontamination and sterilisation of garments – and in the „old" condition – examined after sixty-fold decontamination or sterilisation of the garments.

Method, materials and test procedure

The Body-Box method can be summarised as follows: The Body-Box test cabin measures 1.20 x 1.20 m and is 2.40 m tall. The ceiling is fully equipped with a filter-fan unit (FFU), which in combination with a special floor construction ensures an almost turbulence-free unidirectional flow, so that a very clean environment can be created. The test rig enables the monitoring and adjustment of constant conditions with regard to temperature, humidity and flow velocity.

After a relatively short lead time, constant ambient conditions are created which correspond to the air cleanliness classes 3 or 4 according to ISO 14644). The reference measurements carried out before each test prove the high air cleanliness classes within the Body-Box. If a person enters the Body-Box, all detected airborne contamination is most likely to be from this person and the respective garments worn.

An additional challenge for the upcoming test series with regard to microbiological contamination was to create an environment as sterile as possible before the respective tests inside the Body-Box, but also in the air exhaust duct up to the checkpoints where the contamination was to be measured, in order to exclude cross-contamination and thus measurement inaccuracies. For this purpose, UVC lamps were installed at various points in the test rig. Prior to the respective tests with sterile cleanroom garments, the direct measuring area was irradiated with UVC-light for several minutes, thus achieving disinfection over a large area. In order to ensure that the UVC-light disinfection was correspondingly successful, a so-called reference measurement was also carried out before each test, i.e. with the aid of the particle counter the air flowing through was measured over a longer period of time, thus proving that before a person entered the Body-Box, there was no microbiological contamination at all in the measuring area.

Due to the long experience with the Body-Box method, 10 repeat tests were defined per person and garment system. Every person can emit a very different number of particles and germs, furthermore the range of variation of these emitted contaminations from one and the same person is also very high, so that it is advisable to carry out as many repetitions as possible with the same person and the same garment system in order to determine a representative average value.

Despite these many repetitions, the standard deviation is still high for all measurements. This should not be disregarded in the later interpretation of the determined values. With the help of the Body-Box data, it is certainly not possible

Info box „Measuring method"

The BIOTRAK® 9510-BD from TSI Inc. is based on the autofluorescence method. Using a high quality diode laser of a specific wavelength (violet light), the fluorescence of microorganisms is excited.

Basically, the design of this counter is comparable to that of the well-known optical particle counters. The short wavelength laser (for fluorescence excitation) is the significant difference.

In addition to airborne germs with active metabolism and those in the spore state, damaged and possibly already killed airborne germs are also recorded.
Consequently, the expected measurement results are higher than the results of conventional methods with culture media.

The main advantage of this method is that measurements are taken in real-time and thus possible deviations can be recognised much earlier and corrective actions can be initiated much earlier.

Garments	standing	walking	standing	walking	standing	walking
	≥ 0.5 µm	≥ 0.5 µm	≥ 1 µm	≥ 1 µm	≥ 5 µm	≥ 5 µm
Cotton jogging suit	873,304	34,955,780	657,312	25,114,780	17,077	448,638
Lab coat	331,742	6,304,946	130,901	2,506,495	9,795	101,172
Coverall	28,827	106,328	10,396	32,135	331	851

Table 1: Detected airborne particle during different states of movement. Test person wore different garment combinations.

Garments	standing	walking	standing	walking	standing	walking
	viable germs ≥ 1 µm		viable germs ≥ 5 µm		viable germs ≥ 10 µm	
Cotton jogging suit	1,379	17,893	758	9,368	557	7,367
Lab coat	623	12,496	373	6,474	86	4,847
Coverall	18	263	2	36	2	10

Table 2: Detected airborne viable germs during different states of movement. Test person wore different garment combinations.

to determine absolute values, but „well-founded estimates".

This study involved both a female and a male test person of different body sizes. Initially, 10 measurements were performed per test person with the defined garments, once decontaminated and autoclaved, i.e. in the so-called new condition (first series of tests). To avoid possible effects due to the respective daily form or stress due to repetition, the tests were carried out on several days.

Test rig Body-Box with BIOTRAK®

Summary of the measured values ♀						
Garments	standing	walking	standing	walking	standing	walking
	particles ≥ 0.5 µm		particles ≥ 5 µm		viable germs ≥ 1 µm	
1 x decontaminated	1,489	25,385	12	492	0	141
60 x decontaminated	1,975	37,683	12	716	12	173

Table 3.1: Detected particles resp. germs (extrapolated to m³) for garments in new condition compared to old condition. Female test person.

Summary of the measured values ♂						
Garments	standing	walking	standing	walking	standing	walking
	particles ≥ 0.5 µm		particles ≥ 5 µm		viable germs ≥ 1 µm	
1 x decontaminated	8,477	237,302	35	1,829	0	293
60 x decontaminated	7,584	192,865	43	2,318	14	933

Table 3.2: Detected particles resp. germs (extrapolated to m³) for garments in new condition compared to old condition. Male test person.

For the second series of tests, the test garments were reprocessed several times under defined conditions. The cleanroom garments were decontaminated and autoclaved a total of 60 times. The intermediate garments were decontaminated once. Then, 10 tests per test person were performed again (now in the so-called old condition) according to the defined movement programme. The results are summarised in Tables 3.1 and 3.2 and presented in the form of bar charts in Figures 1 and 2. The Measurement results are, as with all Body-Box measurements, extrapolated to one cubic meter. Due to the large variance in the individual tests, only the average values are shown here.

The movement programme consists of an acclimatisation period of 5 minutes as well as two phases with walking movements on the spot and two phases in which the test person stands still.

The test garments used for this study consisted of the following components:

- for each test person 10 garment sets of ION-NOSTAT VI.2 consisting of a coverall with a full cover hood and overboots
- for each test person also 10 sets of cleanroom compatible underwear/intermediate garments made of Light-Tech II consisting of a long-sleeved top and trousers
- new sterile cleanroom gloves made of nitrile were used for each individual measurement
- also for each individual measurement, a sterile, extra wide disposable, three-layer face mask with defined filtration performance was worn, which completely covered the lower half of the face, as well as defined protective goggles; it was ensured in advance that no open areas of skin could be detected on the face.

Note: No viable germs (V) ≥ 1.0 µm were measured in both test persons when wearing garments in „new condition – standing".

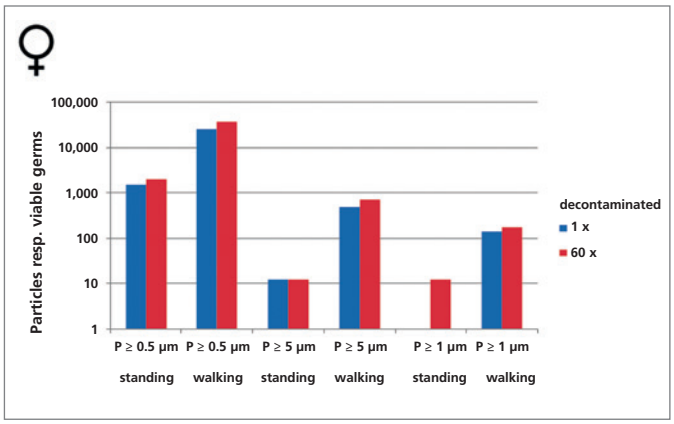

Fig. 1: Particles (P) or germs (V) detected for garments in the new condition compared to the old condition. Female test person.

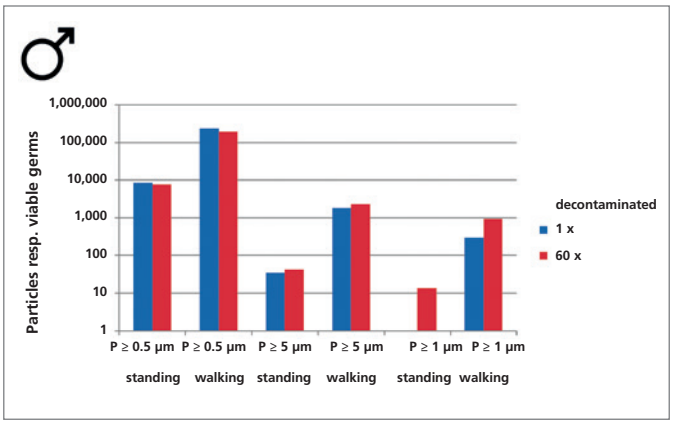

Fig. 2: Particles (P) or germs (V) detected for garments in the new condition compared to the old condition. Male test person.

Results

After 60 cleaning and sterilisation cycles, a clear ageing effect is recognised in the garments. This ageing effect of the garments is reflected in the measurement results of the particles and also germs. A slight increase in particle numbers or microbiological contamination shows that the filtration performance has slightly decreased. The decrease in filtration performance is by no means so critical that an exchange of the cleanroom garments would be absolutely necessary. However, the measured values show that after 10–20 further cycles a change of the garments would most likely be advisable. These results are in line with the many years of preliminary studies of the filtration behaviour of the garment textiles after defined cleaning and sterilisation cycles at the DITF Denkendorf.

On closer examination of the results, it is advisable to include a few more points in the considerations:

- The decrease in filtration performance is most probably exclusively due to the sterilisation process, because other studies with the same method have shown that the same textile shows more stable values regarding the filtration performance, even with a higher number of decontamination cycles.
- It can be assumed that the intermediate garments suitable for cleanrooms „compensates" at least part of the decreasing filtration performance. Further proof of how important cleanroom compatible intermediate garments can be for a clothing system.
- The results only apply to the textiles shown in these test series. Under no circumstances are they transferable to other cleanroom textiles in a general sense. The study from 2015 already quoted at the beginning of this article shows how differently cleanroom textiles, that are similar according to technical documentation, can behave different in terms of ageing phenomena and filtration efficiency.

Conclusion:

The measured values determined with the help of this study are a further proof that a sterilisation process „damages" cleanroom garments much more than the pure decontamination process. The guideline value of about 60 sterilisation cycles (before cleanroom garments should generally be replaced) recommended at various literature references could basically be proven, at least for this textile combination.
It is certainly advisable for end users to carry out similar series of measurements as part of their own quality assurance (or validation of their own garment system), especially if different material combinations are involved.

Literature on request

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