Germ measurements in the Body-Box

dastex
REINRAUMZUBEHÖR

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As is well known, humans are still one of the greatest sources of contamination in clean environments – regardless of whether these are only particulate monitored areas or microbiologically controlled zones. The fact that cleanroom garments thus have a decisive protective function in protecting clean processes from the corresponding contamination caused by people and their personal clothing was impressively demonstrated by a very comprehensive study from 2010, carried out in a so-called Body-Box.

The results (how many particles an employee emits on average per minute, depending on the garments worn and the movement performed) are summarised in Table 1. The question that surely follows from a microbiological point of view, „Can we draw conclusions about possible germ counts on the basis of these figures?" could not yet be answered or substantiated with measurement results at that time. Although there have been some publications on the subject which theoretically deduced a connection, a study with measurement results similar to the measurements on particle emission (see above) did not exist to date. Dastex has now applied itself to this task and carried out a corresponding study in 2014, again using the Body-Box measurement method.

The decisive factor for the feasibility of this last study was the introduction of a new measuring device from TSI Incorporated, the BIOTRAK® 9510-BD. With the help of this meter, it was now possible to quantitatively detect and evaluate airborne germs. How the meter works is described in more detail in the box „Explanation 1". Interestingly, the BIOTRAK® not only allows the quantitative detection of airborne germs, but also the detection of airborne particulate contamination. It was thus possible to differentiate between viable and non-viable contaminants. An interesting question that arose from this was „Is there a direct correlation between particulate contamination originating from a human being and the germ output of the respective persons?", i.e. a kind of conversion factor.

Test person in typical cleanroom garments for GMP A/B areas

Test person in cleanroom lab coat with non-woven bouffant cap over cotton garments

Test person in cotton garments

Study design

Simply summarised, the Body-Box measuring method can be described as follows:
In a very limited environment (dimensions approx. 1.20 x 1.20 x 2.40 m) ultra-clean conditions prevail, due to the construction of the Body- Box (ceiling laid out over the entire surface as a filter-fan unit (FFU) and a special floor construction which ensures an almost turbulence-free displacement flow). A detailed description of the Body-Box measuring method is described and explained in the technical article „A test method on the test bench" (ReinRaumTechnik 2/2004 – GIT Verlag).

Before the actual measurements start, the Body- Box runs in the ‚at rest' mode, i.e. without any persons. In a relatively short time, constant ambient conditions are created which correspond to the air cleanliness classes ISO 3 / ISO 4 (ISO 14644-1). The zero measurements carried out before each series of measurements prove the high air cleanliness classes therein. If a person enters the Body-Box, all airborne contaminants detected are most likely to be of that person and the garments worn in each case. 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 test series inside the Body- Box, but also in the return air ventiduct up to the measuring points where the contamination was to be detected.

Cross-contamination and thus measurement inaccuracies should be excluded as far as possible. For this purpose black-light lamps were installed at different points in the measuring system. Prior to the respective series of measurements with sterile cleanroom garments, the direct measuring environment was thus exposed to ultraviolet radiation for several minutes, thus achieving disinfection of large areas – even in places that cannot be reached with normal wipe disinfection. To ensure that light disinfection in the UV-C range was correspondingly successful, a so-called zero measurement was also carried out before each run.
This means that the counter was used to measure the airflow over a longer period of time and to prove that no microbiological contamination of any kind could be detected in the measuring environment before a person entered the Body-Box.

Three uniform garment systems were defined for the study, which were to be tested repeatedly. Due to the long experience with the Body-Box measurement method, at least 10 repeat measurements were defined per person and garment system. Not only each person can emit a very different number of particles and/or germs, but the range of fluctuation of these emitted contaminations from one and the same person is very high. It is therefore advisable to carry out as many repetitions as possible with one and the same person and one and the same garment system in order to obtain a reliable average value.
Despite these many repetitions, the standard deviation for all measurements is still extremely high. This should not be disregarded when interpreting the values obtained later. With the help of the Body-Box measurement figures, it is certainly not possible to determine „point-exact" absolute values, but rather „well-founded estimates".

Measurement method

The BIOTRAK® from TSI Incorporated is based on the autofluorescence method. A high-quality diode laser of a specific wavelength (violet light) is used to excite the fluorescence of microorganisms.

In principle, 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 counting results are from the outset significantly higher than those obtained with conventional methods using 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 measures can be initiated much earlier.

Number of particles and germs per size per m³ (extrapolated)

	≥ 1 µm				≥ 5 µm				≥ 10 µm			
	standing		walking		standing		walking		standing		walking	
Clothing	particles	germs	particles	germs	particles	germs	particles	germs	particles	germs	particles	germs
Overall	5352	18	93158	263	107	2	1548	36	17	2	132	10
Lab coat	183736	623	3561251	12496	8429	373	174711	6474	1344	86	25888	4847
Jogging suit	571564	1379	8433842	17893	30670	758	456963	9368	5841	557	77007	7367

Table 1

What was studied?

Three typical garment systems were compared. As a starting point, the simple, ordinary street clothes were first examined. This streetwear was simulated with the help of jogging suits made of pure cotton – to obtain a reproducible garment system (for the basic measurements). As a second garment system the „cleanroom lab coat plus non-woven bouffant cap plus cleanroom shoes over this cotton jogging suit" was analysed.

Test rig Body-Box with BIOTRAK®

The third garment system consisted of cleanroom compatible undergarments (a combination of two different materials, each based on synthetic fibres) and the garments, made of a cleanroom fabric as it is usually used in many places in GMP A/B areas (a three-piece – full cover hood plus overall plus overboots). This third garment system was supplemented by sterile nitrile gloves, a sterile disposable face mask and safety goggles, so that no human skin could have been exposed anywhere.

After entering the Body-Box, each test person had five minutes to acclimatise. During this time no contaminations were detected, also under the aspect that of course, when entering the box, contaminants from outside could have been carried over into it. After the five minutes, the measurements were taken in different states of movement, each of them over 30 minutes. Alternately, a slight walking movement was simulated, then a standing on the spot as quietly as possible.

The recorded values were also evaluated accordingly: „standing" and „walking". Taking into account the expected high fluctuation range of the values, at least ten repeat tests were set from the outset per test person and per garment variant. Due to the very high ratio of ultrapure air (continuously supplied to the measuring system via the FFU – Fan-Filter-Unit) and sample volume (a particle counter currently records only 28 litres per minute), the results were finally extrapolated to the actual number of particles or germs per m^3 of air.

Results

Similar to the study from 2010 (in which only airborne particulate contamination was examined), the differences between ordinary cotton garments, the version lab coat plus non-woven bouffant cap and the third version overall, full cover hood and overboots, are striking. Once again it becomes obvious what contamination risk still exists in the cleanroom, both particulate and microbiological.

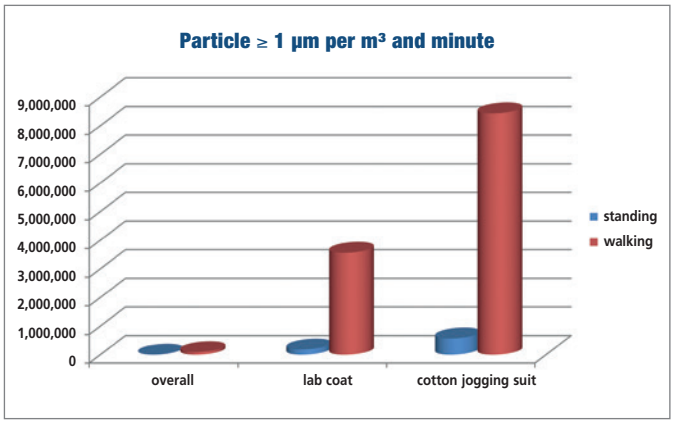
The efficiency of today's cleanroom garment systems has been clearly demonstrated – for germs of the order of magnitude 1 µm and larger – a reduction to about 1% of the initial level and for germs 5 µm and larger even to 0.3%. However, the results also show very clearly that even with very good cleanroom garments, 100% protection or 100% retention of microbiological contamination is not possible.

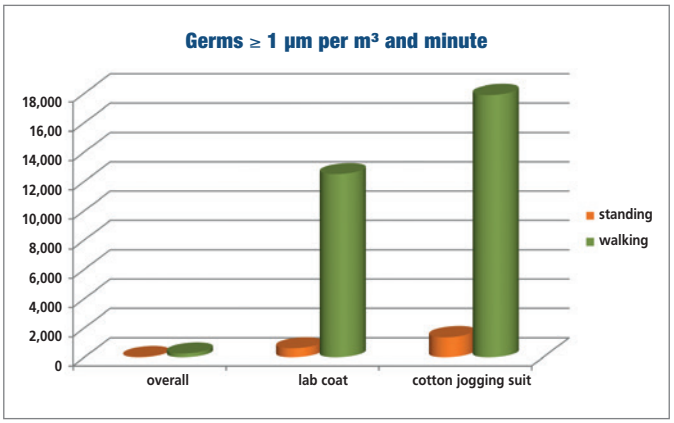
When analysing the particulate contamination simultaneously detected by the test persons with the different garment systems, two points are very noticeable:

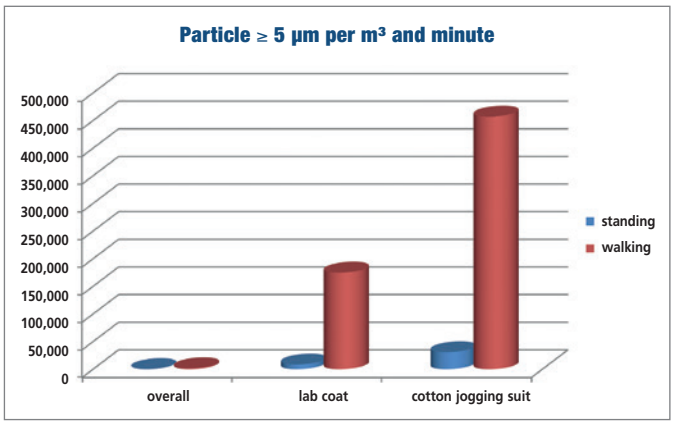
1. It is obvious that persons with high particulate contamination certainly also release a great deal of microbiological contamination into their immediate environment.

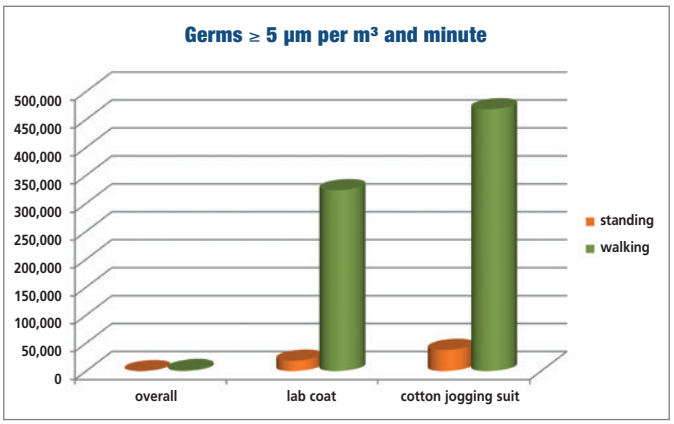
2. A direct fixed coefficient of correlation cannot be recognised from the results obtained so far.

Number of particles and germs per size per m³ (extrapolated)









Interpretation of the results

As there have not been any studies in this direction with the above measuring method so far, a comparison with other study results is not possible. Empirically, however, the obvious hypothesis that high particle emissions from humans are associated with higher levels of microbiological contamination has been empirically proven. Likewise, the good efficiency of a proper cleanroom garment system could be proven.

An interesting question, which can be derived from the measured values determined in this study, is:

„How are the measured values to be evaluated in direct comparison to the many available monitoring data from the different pharmaceutical areas (which usually show significantly low germ counts in ambient monitoring)?
The different measuring methods are certainly one of the decisive factors here.

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