Cleanroom garments:
The residual contamination

dastex
REINRAUMZUBEHÖR

An interface between the cleanroom operator and the cleanroom laundry

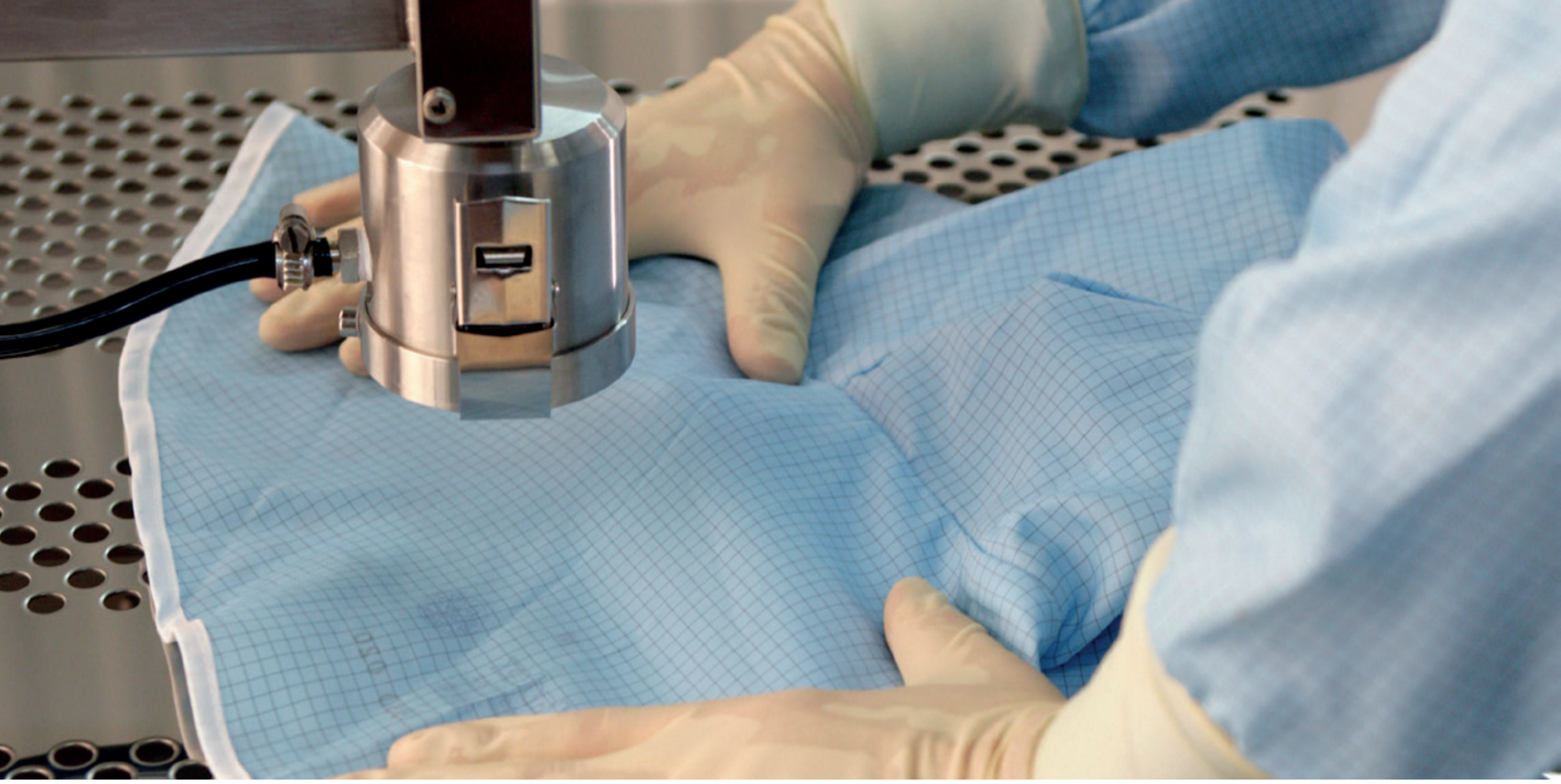
This article describes and discusses the existing system for monitoring and evaluation of residual contamination of cleanroom garments.
It was written after a lecture at the Cleanroom Lounges 2008 in Karlsruhe (Germany) and gives impulses to think about further or alternative procedures and to critically question obvious connections within existing procedures.

When it comes to the determination of the cleanliness classes or the cleanliness in a cleanroom, primarily filter performance, air exchange rates, air velocity, molecular loading of the cleanroom, or the surface cleanliness in the cleanroom are discussed. Strangely enough, the "surfaces" of cleanroom garments are usually left out. In total, the surfaces of all the garments in the cleanroom are certainly a very interesting size, if one assumes that one set of garments means about 4 – 4.5 m^2 surface area. In addition, these are moving surfaces that have an increased tendency to release particles. In terms of quality assurance or maintaining a certain air cleanliness class in a cleanroom, it is therefore appropriate to consider the cleanliness of this surface.

Part 5.1 of VDI Guideline 2083 defines the tasks of textile cleanroom garments as follows: Cleanroom garments are important components of a functioning cleanroom operation. Their primary task is to protect the product from contamination caused by people and their personal garments.

Contaminations

Mainly one speaks of so-called particulate contaminations, i.e. particles that are deposited on the textile surface or are embedded in the textile. However, ionic contaminations, i.e. layer-like contaminations (e.g. oily substances,



The suction method

surfactants, salts, etc.) are also included. In practice, the transition between the two types of contamination is fluid.

How do contaminations arise?
First and foremost, of course, due to our own activities. The body-own particles are released. There are also particles from underwear and possible abrasion from the actual cleanroom textile. However, cleanroom garments also absorb contamination from the environment, i.e. from the cleanroom process, for example machine abrasion. All in all, it can be expected that the degree of contamination varies from garment to garment within very wide limits. In addition, there is the so-called residual contamination, i.e. that portion of "contaminations" that could not be removed during the decontamination process in a cleanroom laundry.

The decontamination process consists of different phases, a first decontamination phase, the so-called washing phase, the second decontamination phase, the so-called rinsing phase, and a third phase, the drying phase.
The level of residual contamination thus depends on various technical factors, such as the washing liquor ratio, the washing machine technology, the number of rinse cycles, the rinsing conditions, the detergents used and the drying technology. The textile to be cleaned also influences the residual contamination level. The reader can find more on this hitherto neglected topic in the chapter "Final considerations".

Testing for residual contamination

In German-speaking countries, two standard measuring methods are used for particulate residual contamination.
On the one hand, the suction method (rapid measuring method) based on ASTM F51-00, on the other hand the so-called "Helmke-Drum-Method". The test values of both methods are assigned to cleanliness classes, which allow an evaluation of the residual contamination level.

Discussion

Due to the different test principles, it is not possible to compare the test values of both methods. They do not correlate, as extensive studies have shown.
But even data obtained from the same method in different laundries are not easily comparable. Reasons for this are the particle counter problem (larger scattering), measuring instruments of different design and different handling methods in the individual laundries or institutes.

With both methods it must be ensured that the particles adhering to the material (surface or pores) are completely detached during the test. In the suction method, the air flowing through the yarn interstices (pores) should ensure this, in the Helmke-Drum-Method the movement (due to bending, torsion, friction) of the fabric. Experience has shown that most particles are detached at the start of the test. The suction method requires a shorter test duration than the Helmke-Drum-Method, but is only suitable for air-permeable materials (this limitation does not exist with the Helmke-Drum-Method).

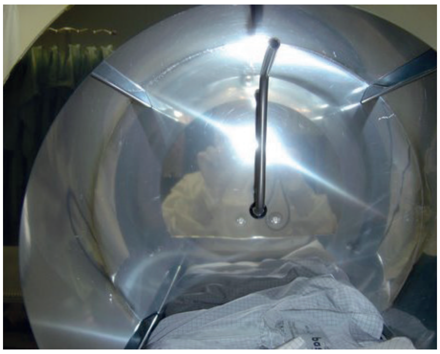
Points of criticism of the suction method

- the determination of cleanliness classes with "relatively large" particles (≥ 5,0 µm)
- the still relatively unclear suction conditions
- the particle detachment only occurs at high flow velocity and is highly dependent on the porosity of the textile

Points of criticism of the Helmke-Drum-Method

- the proportion of the extracted internal drum air is undefined, the same applies to the internal drum surface
- it is undefined how far e.g. a folded overall has to open
- particularly stressed areas of a garment cannot be studied specifically or separately





Loading and starting with the Helmke-Drum-Method

Despite all the points of criticism of both methods, they are suitable for continuous quality assurance in the respective cleanroom laundry and are an acceptable proof of quality for the customer. However, cleanroom operators and decontaminers must decide jointly on one of the two methods, because the characteristic values cannot be converted into one another due to a lack of sufficient correlation.

Other methods for determining the contamination level of cleanroom garments should be mentioned, even if they have not yet become established for determining residual contamination in everyday operation:

- the shaking test (ITV Denkendorf) and
- the Gelbo-Flex Test

Shaking test

In a defined cleanroom the garment to be measured is attached to a suspension device. The suspension device is combined with a shaking apparatus which is set into vibration at a time controlled rate, whereby the particles adhering to the fabric are to be detached. The particle count measuring probes placed in the vicinity of the garment are then intended to detect these detached particles at least partially. Influencing variables in this test setup are the number and positioning of the measuring probes, the shaking frequency and the general air supply (flow principle, air velocity).

Disturbing influences are electrostatic charges due to friction of the textiles during shaking and the particle emission caused by the mechanics of the shaker. The idea behind this test set-up is to use a test method that is as close as possible the stress in use. Due to a lack of interest from the industry, this method could not establish itself.

Gelbo-Flex test

In this process, too, the particles are released by mechanical stress. So far, however, only pieces of fabric can be tested and not whole pieces of clothing. The test item is located in a test chamber through which ultrapure air flows (with defined air exchange). It is compressed and rotated by 180° at 60 cycles per minute. A measuring probe extracts the particles emitted by the load and a downstream particle counter records their number. A critical point to note is that the ratio of ultra-pure air to sample volume influences the measurement.

In order to be able to test entire garments by means of an adapted Gelbo-Flex test, the test setup would have to be changed significantly at various points. A hood or overboot would certainly behave differently than an overall or gown. Initial considerations to adapt the Gelbo-Flex test were also rejected due to lack of user and industry interest. As a result of standardisation in the medical field, interest has recently increased again.

Online monitoring

The measuring methods presented so far are applied to the testing of individual garments taken randomly from a washing batch. Alternatively, it would be possible to check certain parameters during the ongoing decontamination process. For such an online monitoring, the monitoring of the waste water would be suitable, whereby the particle content in the last rinse bath would be recorded by means of a liquid-borne particle counter. One could also consider monitoring the exhaust air in a tumble dryer.

Such a monitoring system would ensure that an entire batch, i.e. the complete contents of the drum, would be checked and not individual items of clothing. Such a change would correspond to a system change with far-reaching consequences: The cleanliness classes would be useless.

Since there are no empirical values for either method, basic data would first have to be determined in advance over a long period of time in order to be able to classify later results. Even with such a measuring method, it can certainly be assumed that different fabrics produce different values. This also applies to changes in the process, such as different loads or the different concentration of the detergent.

Test series on the contamination level

Finally, the questions:
When should a cleanroom garment generally be sent for decontamination? Is it possible to determine the contamination level of a cleanroom garment directly at the customer's site? This is not so much about cost optimisation! Rather, it is a matter of sensitising users and decision-makers to give the garments into the decontamination process in good time and thus to protect their processes. Often, certain items of clothing hang in garment sluices for weeks and thus in undefined environmental conditions. They are exposed to cross-contamination and become a contamination risk for the products to be protected when they are then worn again in the controlled area.

In a first series of experiments, the Institut für Mikroelektronik (in Stuttgart) and the companies CCI – von Kahlen, Micronclean Deutschland (Reutlingen) and Dastex have tried to carry out particle measurements on the surface of garments (overalls) using a surface probe. At the same time these measurement results were compared with the studies on a measuring table according to the suction method. For this purpose, 15 overalls were examined at eight measuring points each before and after use. A working day with repeated dressing and undressing procedures was determined as the duration of use for one overall. The environmental conditions at the Institut für Mikroelektronik are similar to those of classical microchip processing (ISO 5). Unfortunately, the knowledge gained so far is not clear. Although the control measurements using the suction method showed a clear increase in contamination values after just one day in worn condition, the measurements using the surface probe were different. In some cases, even low particle concentrations were measured, i.e. the measurements had a very large scattering. The findings obtained in the test phase show two main influencing factors: the contact pressure of the probe on the measuring surface and the positioning of the probe on a smooth, mainly wrinkle-free surface, which was very difficult to perform in practice.
For the further development of this measuring method, the number of measuring points must be reduced. The persons carrying out the measurements must be trained in detail in advance for positioning and contact pressure of the probe.
With regard to a continuous improvement in the production process, or to a better control of the environmental conditions in the actual cleanroom process, it would certainly be helpful if the contamination level of the cleanroom garments could be checked randomly before entering the cleanroom.

Final considerations

Unfortunately, other aspects have not been taken into account in the decades of discussion about the proper residual contamination testing technique. However, in view of the increasing requirements of cleanroom operators and cost pressure, they can no longer be neglected. From the cleanroom laundry's point of view, this concerns at least three topics:

1. Contamination level and residual contamination level

To what extent does the achievable residual contamination level depend on the contamination level of the worn coveralls, i.e. the degree of contamination of the worn coverall? In other words: Is it possible to achieve a constant level of residual contamination, regardless of the level of contamination? Or does the degree of contamination - analogous to the basic rules of filter technology - determine the level of residual contamination because the cleaning effect is a fabric-specific characteristic and is 99.99%, for example?

2. Fabric batches and decontaminability

In the overall equipment of a factory or an area (department) there are usually overalls of different ages, whereby experience has shown that a practical eighty decontamination treatments correspond to a three-year to five-year period of use. If overalls are replaced successively over such a long period, overalls of the same type will inevitably come from different fabric lots. The properties of several batches of fabric (from different manufacturing periods) will of course correspond in the specified characteristics. However, it cannot be ruled out that other, uncontrolled characteristics may vary within certain limits: so far, this includes decontaminability, due to the lack of a defined testing technique. Does this mean that significant fluctuations in residual contamination must be expected due to batch-dependent differences in decontaminability?

3. Fabric ageing and residual contamination

Overalls for highly classified cleanrooms are characterised by a curiosity: On the one hand they consist of particularly high-quality fabrics, on the other hand hardly any other textile is subject to greater stresses of care (probably even in connection with sterilisation) than an overall. Depending on the frequency of use, significant material ageing must therefore be expected. To what extent do the successive ageing and the achieved state of ageing of overalls affect the decontaminability and thus the residual contamination level?

Such questions show some of the possible directions of development, whereby it must be considered that basic knowledge must also be acquired. The field of work therefore remains exciting for all those involved. This includes cleanroom operators, cleanroom laundries and the developers of cleanroom textiles, as well as of measuring and treatment methods for cleanroom garments. The invested effort promises worthwhile progress towards increasing process reliability and cost efficiency.

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