



*In 2014 the Fraunhofer Institute for Manufacturing Engineering and Automation IPA initiated the idea of founding an association of the cleanroom consumables industry entitled "Cleanroom Suitable Consumables". Prior to this, an essay was published by the same institute [1] in which the authors assert that cleanroom consumables have an "immense" effect on the purity of the production environment and that to date, no uniform methods exist to test and assess the consumables. This essay is a response to the surprising statements by the Fraunhofer IPA Institute.*

## Are Cleanroom Consumables Dangerous Sources of Contamination in Cleanroom-Operations?



Win Labuda



Lodevicus Hermans



Heinz-Josef Kiggen

### Cleanroom consumables

Cleanroom consumables include: *disposable and reusable clothing, cleanroom gloves, cleanroom wipers and swabs, cleanroom paper and notebooks, disposable breathing masks, cleanroom shoes, mopping systems and cleanroom packaging material.*

Manufacturing processes that take place in cleanrooms require clean consumables – that is the current doctrine. Just how clean is a hitherto unanswered question. Due to this uncertainty most of the cleanroom consumables are decontaminated to a high degree during their manufacture. But even afterwards, traces of contamination can be found on the surfaces. They may get into the sensitive core areas of the process and reduce the process yield. The following three examples from practice illustrate this relationship.

- If dust particles get into the clockworks of wrist watches, the movement of the clockwork is inhibited and the watch stops.
- If particles or thin oily layers are found on the camera lens, or in particular on the light-sensitive surfaces of the image sensors, the quality of the image suffers.
- If during production, particles, germs and other foreign substances get onto the surfaces of wafers, precarious failure situations may occur in steering the aircraft or vehicles or in medical equipment.

**General quality assessment of cleanroom consumables**

If we had to assess the quality of cleanroom consumables currently in use without the aid of measuring equipment, three arguments in favor of the quality of the existing consumables would occur to us:

The semiconductor industry – utilising by the respective cleanroom consumables – has achieved an impressive development over the past quarter century. This is the best proof for the sustainable general purity and usability of our cleanroom consumables.

As a matter of principle, high-tech industries do not use consumables which could reduce the process yield out of their own interest. This would inevitably be noticed, and they would be eliminated immediately by the defect engineering system or a benchmarking team [2, 3].

An adequate selection of lesser or higher quality consumable products is available in the market (Fig.1), so that the degree of contamination related to consumables can be easily influenced by choosing the right consumables for the appropriate purpose. Tim Schärff described this in his article [4].

To demonstrate the various influential factors we have established the following variables:

- PP            Process Purity
- CQ tot       Total Contamination quantity
- CQ spec      Contamination of a particular consumable
- PY tot       Total Process Yield
- PRYR        Product-related yield-reduction

**Contamination and its spread**

The process purity  $PP$  is characterised by the total contamination quantity  $CQ_{tot}$  which, if exceeded, will impair the functionality of the system [5]. From this we can derive that all clean systems are related to the respective individual process. This hypothesis contains the variables with respect to our topic.

Thus, the process yield  $PY_{tot}$  is a function of the effective total contamination quantity  $CQ_{tot}$ . However, because the total contamination quantity  $CQ_{tot}$  is comprised of different individual contaminations, in the best case of the above mentioned variables, we only have access from a metrological perspective to the specific contamination quantity  $CQ_{spec}$  and the total process yield  $PY_{tot}$ .

In a production line under cleanroom conditions, cleaning and regular control of the cleanliness conditions have the sole purpose of ensuring the optimal process yield. Therefore, one could draw the hasty conclusion: the purer the consumables, the higher the process yield. However, a connection between the purity of the consumables and the process yield has hitherto not yet been described in literature. It is merely probable that with increasing contamination of the consumables the process yield decreases. It is also conceivable that this function is tied to a process-specific threshold value (see Fig. 2).

A complicating factor in the establishment of an integral purity system is the fact that the

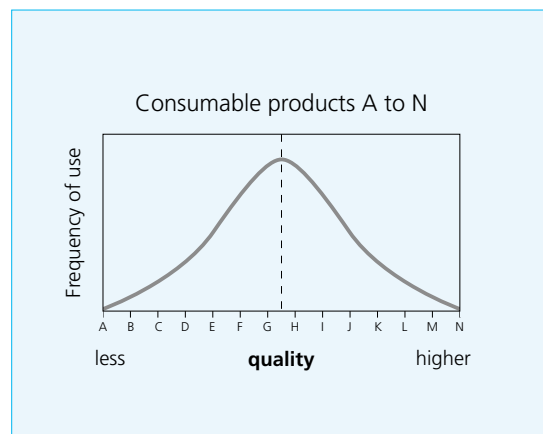


Fig. 1

dispersion channels of contamination in the production environments of high-tech industries are difficult to trace. This also applies to chemical contamination (ACC) and molecular (AMC) contamination [6]. They are determined to a great extent by fluctuating electric fields, moisture conditions, forced airflows, changing temporary resting sites of the particles by their surface structure and possibly also by the operator's handling.

From all this it follows that a correlation of the consumables-related contamination to the process yield reduction cannot be made as a matter of principle. (see Fig. 2).

**The process as a cybernetic system**

For instance, if we consider the semiconductor manufacturing process a flexible cybernetic system, with the process description we define a certain number of materials, process steps and setpoint values, all of which are oriented on one process goal: the continuous production of wafers with a yield greater than 98 % on the basis of a certain "cost-per-wafer" specifications.

The choice of excipients, of the process steps and the determination of the target values are based on process experience with the same or similar processes. They are oriented on the respective technical state of the material and excipient systems. If the use of a specific consumable therefore regularly shows a certain amount of contamination, this has already been considered as far as process technology is concerned. The process objective is not jeopardised by the *regular contamination* of the consumable. Rather, the danger for the process continuity arises from potential catastrophic events, which can increase the effective contamination in some sites of the process drastically – for instance, when a glove manufacturer accidentally delivers powdered gloves instead of cleanroom gloves and this remains unnoticed. This may cause contamination peaks during production, which may also turn out to be process relevant. However, such incidents are rare and can hardly be avoided. They could only be influenced by automated rapid measurement systems, but their use would hardly be appropriate from an economic perspective considering the relatively

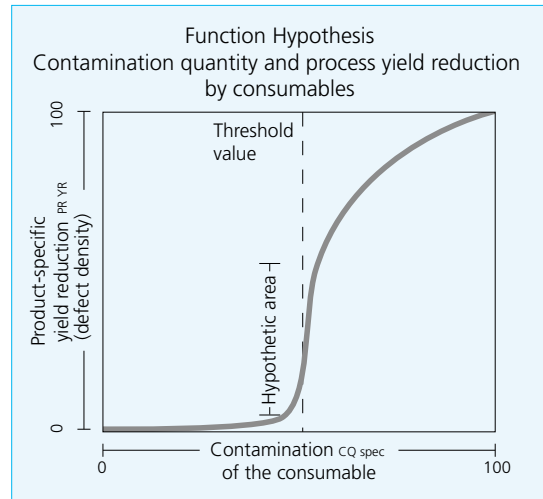


Fig. 2

low potential risk. Once a well-coordinated "team of materials" with respect to process technology has been established, the process leader must weigh economic against technological considerations and decide whether to keep the existing product mix or to switch to a less expensive consumable which will then potentially lower the cost per wafer.

**Only a very small part of the contamination in the manufacturing environment is process relevant.**

The fact is that upon delivery, every cleanroom consumable – even decontaminated consumables – still has residues of particles

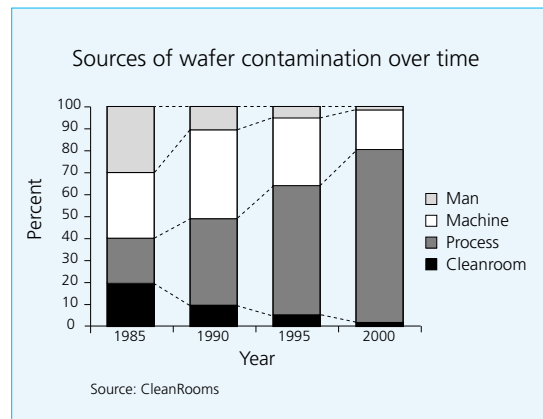


Fig. 3

and film-like contamination. This contamination, however, is much less than assumed. As shown below, there are a number of reasons for this:

The only contamination that is process relevant is the one that reaches the manufactured product from the consumables via the production environment, contributing there to a reduction of the process yield.

Due to technical progress, since 1985 the percentage of cleanroom-generated contamination on wafers has dropped from 20 % to 2.5 %. [7] This naturally reduces the risk of contamination elicited by consumables (Fig. 3).

On the way from the surfaces of cleanroom consumables to the contamination-sensitive core areas of the process, the possible spread of particles will be limited by the *process-specific contamination barrier* [3, 5]. The effective factors of the process-specific contamination barrier in the semiconductor production process are, for instance, the hermetic isolation of the process (SMIF), the laminar airflow and the number and duration of rinsing and etching procedures in the process as well as the regular cleaning of cleanroom surfaces. The spherical expansion of the existing particle clusters also leads to a reduction of the contamination density. This is particularly true for the increase of the spatial distance between the production environment and the core area.

### Comparative quality assessment

Since an association between consumables contamination and process yield has not been described, for us only hitherto comparative quality assessment remains to establish the harmlessness for the use of certain cleanroom consumables. For this purpose, the surface contamination of consumables known to be problem-free and used for optimized process yield is analytically determined. The thus determined contamination data then serve as benchmarks for comparable products or products to be developed.

Two methods of particle measurement with regard to cleanroom consumables have gained acceptance in the past decades:

- *The modified Gelboflex test* according to DIN EN ISO 9073-10 [8] is an adhesive force-neutral test method for detecting motion-induced particle release for *cleanroom wipers and films*. *Adhesive force-neutral particle release* means: Those particles will be counted that are dispersed naturally in the environment when using a consumable. However, the Gelboflex simulation-equipment is unsuitable for the simulation of very low values of mechanical work as performed when folding a cleanroom wiper twice before its use.

*"We should not forget that the aim of all cleaning-by-wiping-procedures is to provide clean surfaces and not clean wipers. Our metrology must therefore be focused on surface contamination before and after the wiping procedure rather than on contamination of the wiper."*

Win Labuda

- By contrast, IEST-RP-CC 4.3 is the method mostly specified and used for the determination of particles in cleanroom wipers. Here the consumables are immersed in a liquid bath. This method to release the adhesive forces was conceived a long time ago. In doing so, false high particle counts were generated, which can amount up to 10,000 times the number of particles dispersed in the environment that are counted using adhesive force-neutral test methods. Existing test methods for the particle release of cleanroom consumables such as those according to IEST are usually of the adhesive force-releasing type. This means: The particles are rinsed off e.g. from the surface of a cleanroom consumable using DI water. Thus, the van der Waals adhesive forces are neutralised, a large part of the particles is released and then a counting process takes place.

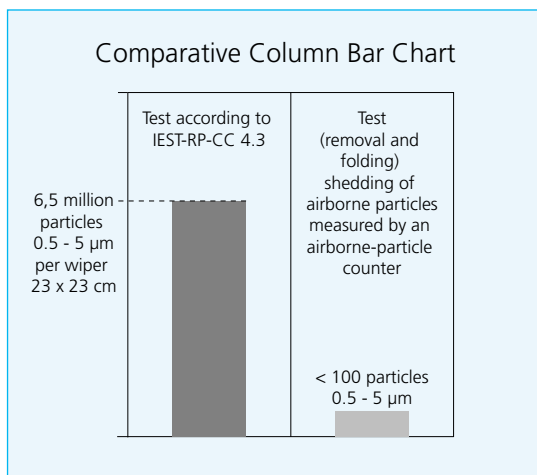
With regard to the current discussion on test methods, we have referred first and foremost to the tests for cleanroom wipers. However, "recommended practices" of the IEST - Institute of Environmental Sciences and Technology, USA have existed for many years also for other cleanroom consumables [9]:

IEST-RP-CC003 Garment Systems (Helmke)  
 IEST-RP-CC004 Wiping Materials  
 IEST-RP-CC005 Gloves and Finger Cots  
 IEST-RP-CC025 Swabs

These methods are cited by both the consumables manufacturers as well as by the customers as basis for the agreed upon delivery quality. Also there is a US-Specification A-A-59323 A (CID) for cleanroom-wipers to be used in the US-Navy and other US Federal Agencies.[16].

#### Here we are in a dilemma:

The physical basis of some IEST methods – that is, the release of adhesive forces – produces unrealistically high particle counts. In this respect, these methods certainly need revising. However, the IEST methods have the advantage that they can be carried out with relatively simple and inexpensive means. Proponents for retaining them argue that if any newly developed equipment and methods cannot be related to the process yield parameter anyway, a modification of the existing test methods is not justifiable.



**Fig. 4**

#### Comparison of methods and results

Below we compare particle release data using two different test methods:

In the immersion test according to IEST-RP-CC 4.3 for cleanroom wipers, from the total volume of a cleanroom wiper with the dimensions 23 x 23 cm made of a polyester-cellulose blend, 6.5 million particles 0.5 - 5 µm in size were extracted. At first glance the number conveys the impression that cleanroom wipers are "the sources of contamination in clean production areas" (Fraunhofer IPA).

In testing the particle dispersion in the clean workbench, for comparative reasons we have measured the actual airborne particle dispersion which emanates from a standard cleanroom wiper. Then a completely different picture appears: We found for the process of package removal 64 airborne particles 0.5 - 10 µm in size and for the process of twice-folding, another five particles. Even if with this method, due to the measurement geometry, not all of the dispersed particles could be counted by the counter sensor, we can conclude from this that there are significant differences in the number of released particles, and that it is not unreasonable to advocate a revision of the test methods for cleanroom consumables. (Fig. 4)

#### Simulation of the mechanical work by means of the test equipment

In developing or selecting test equipment and methods, we always need to be aware of the dubious test results which can arise (see Fig. 4) when the simulated mechanical work of the test equipment does not correspond to the stress during the application of the consumables. This is not only the case with the test method IEST-RP-CC 4.3 (for wipers) [10], but in principle also with ASTM F51-68 (test method for clothing) and IEST-RP-CC-005.3/4 (for gloves).

The uncertainties in the perception of the quality of cleanroom consumables often arise from false-positive test results due to inappropriate test methods. To obtain realistic contamination data through simulated use stress, the mechanical test must first render results that are equivalent to those of actual use. The

guiding principle must be to simulate with a test device the mechanical work in the practical use of consumables with a high degree of simulation fidelity [10, 11].

If this prerequisite is not met, the consumables manufacturer cannot subsequently reduce the flaws in the production of the consumables to the required level.

Furthermore, for the simulation of particle dispersion, it is absolutely essential to identify the *test medium* and the *release medium*. Otherwise – as occurred in the IEST-RP-CC 4.3 test method – the particle dispersion of the dry wiper into the environment through the particle release of the wet wiper into the DI water will be falsely simulated.

### The consumables market – trends and statistics

To estimate in advance the possibility of establishing revised test methods also internationally, it is worthwhile to take a look at the geographical distribution of the leading technology markets. If these do not want new methods, it will hardly be possible to push these through. The increase in demand for cleanroom consumables has mainly taken place in Asia in the past decade [12]. By the



Fig. 5 Labuda Filling Simulator Mark 1 (Clear/Clean)

end of 2015 the demand in Asia for cleanroom consumables will have grown from 3.7 (2011) to max. 4.6 billion dollars. For the same time period, only 1.5 billion dollars respectively are projected for the European and U.S. demand. Therefore, it is hardly to be expected that manufacturers in Asia will give up their quality assurance systems on the basis of IEST Recommended Practices of European conception. There would have to be a good reason to do so, since the yields in Asia are known to be close to 100 %.

### VDI 2083 Sheet 9.2 – a didactic work

The new VDI directive is a valuable contribution to the techniques of clean work. It is due to Carsten Moschner's [13] eloquence and especially his unmatched diplomatic talent, but above all due to the experienced staff of the VDI Guidelines Committee, that a work of this scope has been realised. However, the topics of measurement and testing regulations were omitted, and a few of the statements in the introduction appear somewhat ambiguous. It therefore seems appropriate to first internalize and apply the new directive for a time while it is still in the draft stage. The directive is instructive for anyone who deals with cleanroom consumables as a student or professional. Anyone who applies the knowledge compiled in it to clean technological tasks can understand the relationships better and can cope with the increasing tasks in practical operations with relative ease.

Therefore, probably no additional specifications or regulations are required for the determination of a particular quality-level if we assume that the use of cleanroom consumables must anyway be planned specifically to relate to the process. Perhaps it would be sufficient to add an appendix "Measuring and Testing" to the existing directive, accompanied by general recommendations.

### Different cleanroom operations - semiconductor industry in comparison to pharmaceutical industry

Next to the semiconductor industry, the pharmaceutical industry is the most important user of cleanroom consumables. While in the semiconductor manufacturing process the existing process-related contamination only has an

economic impact on the process, contamination in the production environment of the pharmaceutical industry may potentially have adverse effects on human health. In particular, microbial contaminants are the differentiating factor between cleanrooms of the pharmaceutical industry and those of the semiconductor industry. Therefore, laws and regulations have been adopted by many countries to take this fact into account. Pharmaceutical compounding, for example, is legally regulated through comprehensive guidelines of Good Manufacturing Practice. But the diverse editions of Pharmacopeia have hardly ever covered the cleanroom materials to be used.

However, in the 2008 edition of the U.S. compendium Pharmacopeia (USP Revision Bulletin 797) the following requirement is stated: "All cleaning materials, such as wipers, sponges and mops, shall be nonshedding ...". Strikingly, the reason why the authors of Rev. Bull. 797 made this requirement is not given. In principle, they would have to know that no wipers exist that are "nonshedding", i.e. free of particle scattering, unless they are in a solvent-soaked state.

Be that as it may: In the May/June 2015 issue of the U.S. Journal "Controlled Environments" the author Jan Eudy – formerly president of the IEST – reports that in the U.S. auditors have recently demanded validation documents showing that the used cleanroom wipers, in compliance with USP Rev. Bull. 797, are nonshedding and lint-free. As proof, the wiper manufacturer would be required to enclosed analysis certificates. To our knowledge, no generally recognised application-stress-equivalent test method currently exists to determine the shedding of particles and fibre fragments although such a method is described in the literature. This method, however, does not fulfil the attribute "generally recognised" [12], fig. 5. The responsible body of the IEST – working group 4 – is currently conferring on this matter (July 2015) and intends to provide a revised "Recommended Practice" for cleanroom wipers by autumn of this year in which the auditors' demands are taken into account. One must carefully observe what impact this matter will have on the development of cleanroom consumables for applications in the pharmaceutical industry and whether the au-

thors will specify further quality requirements for cleanroom consumables in the future.

Also this example makes clear that the pharmaceutical industry is already subject to closely monitored regulations. Any further material specifications and certificates would have to be integrated into the existing regulation handbooks, and this is not to be expected unless there is a justified and carefully documented reason for this.

### Summary

- We note that neither the resting sites nor the dispersion pathways of particulate contamination in the production environments with a high degree of ambient purity are usually predictable or traceable. Under these circumstances, any potential contamination effect on the process yield must be classified as "process specific". This assumption also applies to chemical, molecular and ionic contamination.
- We were unable to recognise a causal relationship between consumables-related contamination and process yield or derive such a relationship from the reference literature. Thus, according to the current state of technology, a generalised establishment of product-specific contamination limits for cleanroom consumables is not indicated.
- The establishment of test methods and contamination limits for cleanroom consumables is nevertheless possible with methods of comparative quality assessment. But even the comparative methods are only feasible if an adhesive force-neutral test methodology is used and moreover if the testing equipment simulates the specific mechanical work equivalent to the use-load of cleanroom consumables.
- We introduce the term *process-specific contamination barrier*. With this concept, we describe the symbolic effective inhibition of all active factors in relation to the spreading of the process-specific contamination. This includes [8] the hermetic isolation of the process (SMIF, Standard Mechanical InterFace), the laminar airflow, the handling by a trained operator, the number and duration of the etching

processes, the regular cleaning of the cleanroom surfaces, the reduction of the contamination density through the linear or spherical spreading of the contamination and the spatial distance between the manufacturing environment and the core area.

- A portion of the raw materials for the production of cleanroom consumables such as nonwoven fabrics and yarns are manufactured as "roll goods" in large plants. When placing the order, manufacturers of consumables have the possibility of specifying basic parameters such as fibre mix, thickness, maximum tensile force and surface-related mass, but not, however, clean-technical parameters such as particle dispersion, ion count and degassing parameters. This possibly explains the reaction of the author Moschner [13] who – surprised by the outcome of a series of tests of different cleaning wipers he performed – had to concede that the same raw materials may show significant differences with regard to particle release. However, these are usually not caused by the manufacturers of the consumables, but rather through the raw material process and also often through the different measurement techniques.
- In the cybernetically conceived process system, each consumable material represents a potential process-relevant contamination. However, through process-technical measures, this is reduced to the extent that the regular contamination by the consumables is not process relevant but rather system immanent. Potentially process relevant in the sense of counterproductive is only the rare catastrophic contamination, which cannot be controlled by the normal means of process technology and whose removal requires special measures.

#### Examples of manufacturer-based tests for consumables and other test concepts

From various sources there are approaches to reasonable testing methods. Below some of them are described briefly:

*Body Box (modified) by Moschner and von Kahlden*

Measurement of motion-induced particle dispersion from cleanroom clothing [14]

*CCI air flow sensor with scattered light counter*

Measurement of the quantity of particles stirred up by the air flow stream directed at the surfaces

*"Part-Sens" Particle Counter according to Klumpp*

Particle counter to detect particles on surfaces based on light scattering methods

*Labuda Fulling Simulator Mark 1 (Clear/Clean)*

Measurement of particle dispersion via the bending load of porous sheets [11]

*CCI-Particle-Visualization-lamp*

for the visualization of particle layers and single particles in scattered light.

*Labuda Indicator Plate (Clear/Clean)*

Dark-coloured plate to make thin films and particulate contaminants visible [15]

*Labuda Particle Lift Collector (Clear/Clean)*

Collector to take up layers of material particles from surfaces for subsequent counting

#### Authors

*Hermans, Lodevicus*, physicist, Diploma in 1979 at the Technical University of Eindhoven; for 35 years Mr. Hermans has been a Siemens/Infineon Senior Staff Engineer for Contamination Control, Infineon in Regensburg

*Kiggen, Heinz-Josef*, physicist, Doctoral degree in 1979 at RWTH Aachen, for 32 years Dr. Kiggen has been Quality Manager, Texas Instruments in Freising

*Labuda, Win*, author specialized in cleanroom technology, in 1979 founder of Clear & Clean Werk für Reintechnik GmbH, 35 years of experience in manufacturing cleanroom consumables

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