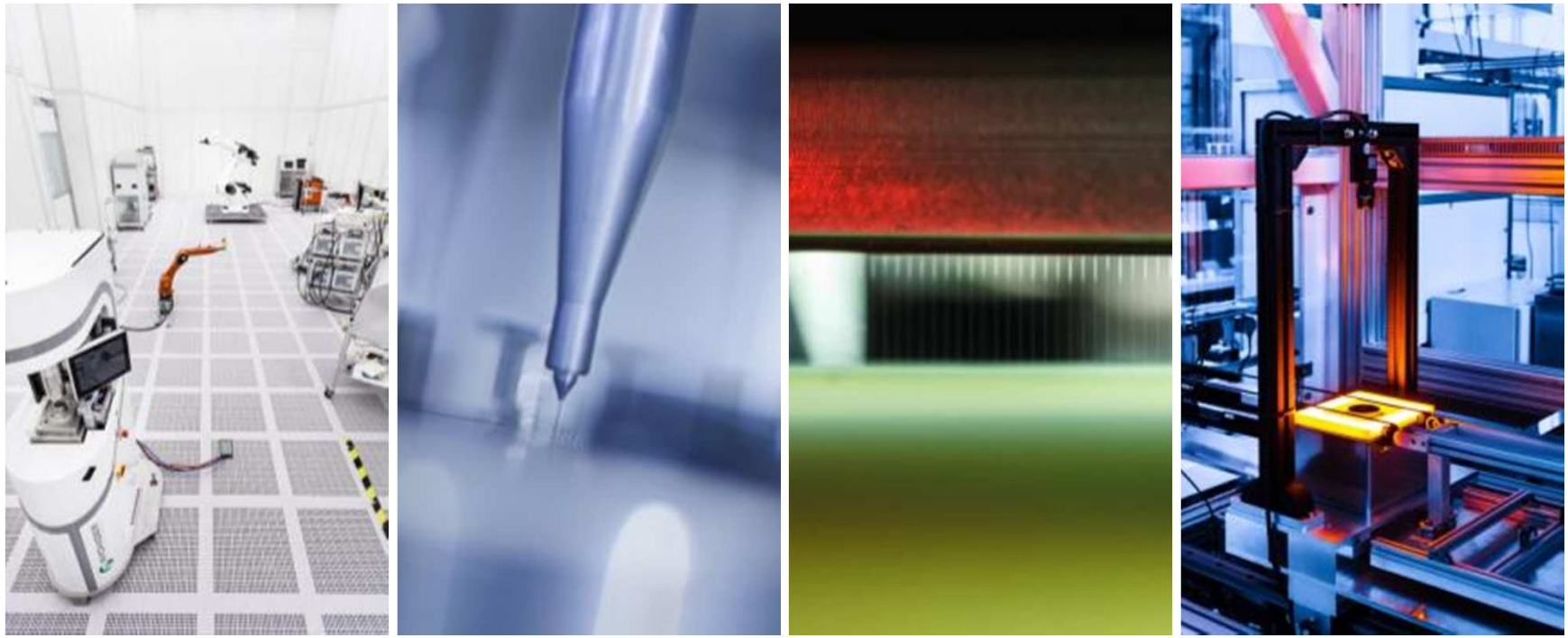
ULTRACLEAN TECHNOLOGIES AND MICROMANUFACTURING

Fraunhofer Institute for Manufacturing Engineering and Automation IPA
Dipl.-Ing. Guido Kreck



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WP3400:
Cleanliness Analysis of Robotic Arm and End-Effectors

Task:

- Provide introduction to analysis task that will be completed by Fraunhofer IPA
- Research design of proposed Robotic Arm (KUKA LBR IIWA 7 R800/R820), estimate level of cleanliness and compare cleanliness to cleanest robotic arm available (e.g. Kawasaki MSR05)
- Assess methods that can be used to make proposed Robotic Arm (KUKA LBR IIWA 7 R800/R820) to have improved levels of cleanliness
- Research design of proposed End Effectors (TBC), estimate level of cleanliness and compare cleanliness to cleanest End Effectors available
- Assess methods that can be used to make proposed End Effectors to have improved levels of cleanliness
- Outline general guidance for modification of equipment for use in the ultra-clean environment of a Double Walled Isolator

Output:

- Cleanliness Analysis of Robotic Arm and End Effectors

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Analysis Tasks

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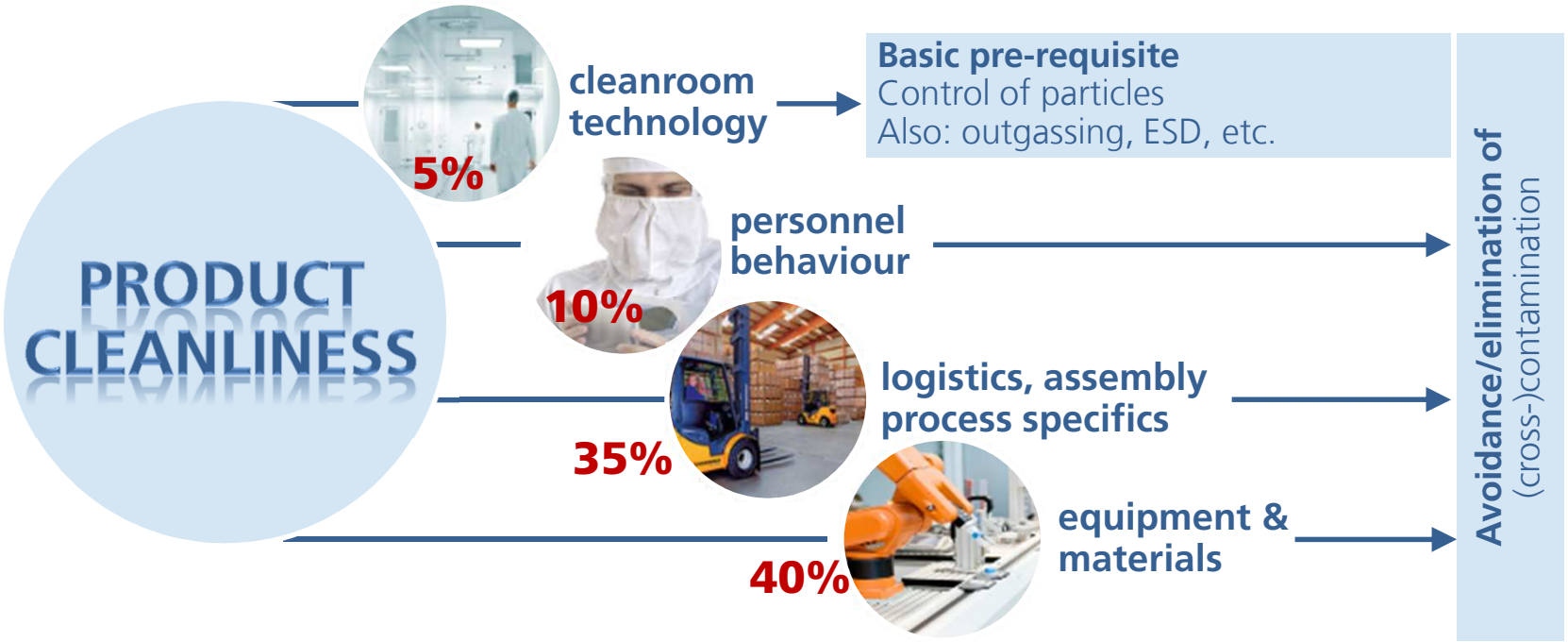
What to take care of?

- **Main task of cleanroom**: to reduce airborne, particulate contamination
- **False** assumption: ~~a cleanroom itself will solve all my contamination problems~~
- **Better** approach: **product** and it's cleanliness specifications = **middle of the consideration**

Causes of contamination, trends in cleanroom operation



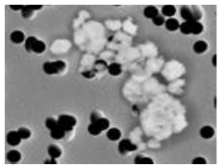
- Cleanroom technology = basic pre-requisite
- Assembly, processes, equipment, staff, … as sources of contamination
- ➔ Contamination sediments onto surfaces
- ➔ Storage and risk of transfer to other objects
- ➔ Avoidance and, if applicable, elimination strategies

Critical Contaminants

Particles

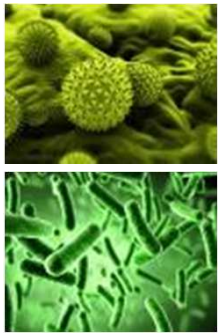
abiotic

- manufacturing process residues (dust from abrasive processes, abrading agents, …)
- dust from the environment
- extraterrestrial samples
- etc.



biotic

- bacteria
- spores
- flakes of skin & cell fragments
- etc.



Molecular

filmic (organic & anorganic)

- residues from auxiliary production materials (cooling lubricants, preserving agents, …)
- fingerprints
- etc.

COMBINATION

Microelectronics (incl. ESD) + Life Sciences

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Required Tests

1. **Particles** – requirements for cleanroom suitability
   Requirements derive from particle cleanliness specs acc. to **ISO 14644-1**
2. **Outgassing behaviour**
   To minimize influence on production process, outgassing potential of equipments must be defined.
   Classification acc. to **ISO 14644-8**
3. **Cleanability** of equipment surfaces
   Ability to clean contaminated equipment-surfaces (reduction of particle cont.) will be described by SCP-classes, as defined in **ISO 14644-9**
4. **Chemical resistance**
   Requirements for the chemical resistance of used equipments should be described by details of resistance figures, as defined in **ISO 2812-1**
5. **Hygienic Design**
6. **Airflow visualization/simulation**
7. **H2O2 absorption/desorption**
8. **Riboflavin test to assess cleanability**
9. **Microbiological Resistance and Microbicidity**

Aim:
assess the cleanroom suitability of operating utilities

- **Wrong:** ~~product has air cleanliness class ISO Class 4!~~

➔ Operating utilities **do not** have an air cleanliness class

➔ **Suitability for use** in defined air cleanliness class

- Reason: air cleanliness class = concentration of contamination per volume of air
- **Air cleanliness class:** characterizes only quality of first air in a cleanroom

➔ Operating utilities: do not generate a volume of air!

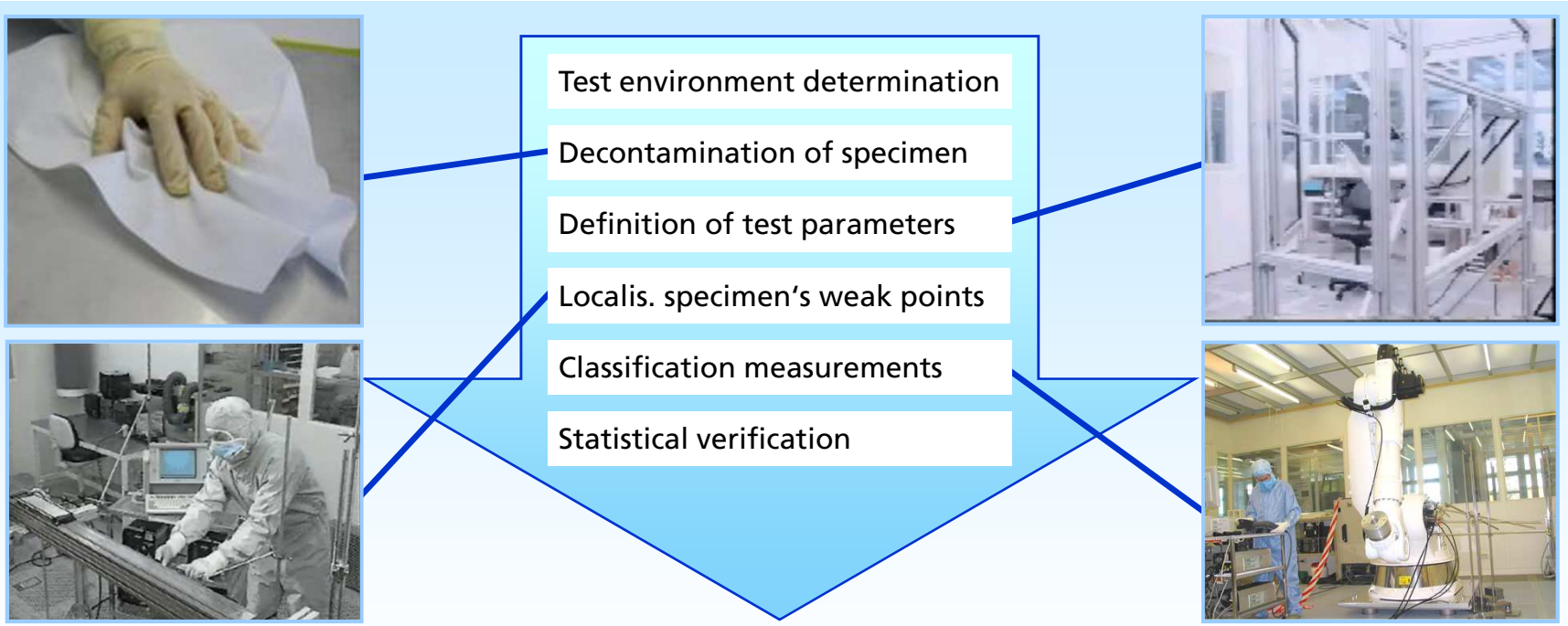
Source: KUKA Roboter GmbH

➔ Operating utilities: **do not fulfill an air cleanliness classification**

➔ **Standardized procedure for cleanroom suitability tests with clear meaningful interpretation of results needed**

- **Solution:** implement the guideline VDI 2083: Part 9.1 »Compatibility with required cleanliness and surface cleanliness« (previously Part 8)

1) Measurement Procedure to classify Equipment for their Cleanroom Suitability (particle behaviour)



- Classification in regards of particle emission: production equipment **is suitable for its use in cleanroom class »X«**
- False statement: ~~production equipment has a cleanroom class »Y«~~

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2) Outgassing behaviour of used Equipment Materials

To find out about the **suitability of equipments** to be used in **AMC-controlled environments:**

➔ emission behaviour of equipment has to be determined

Critical components for clean applications:
Amines, Phthalates, Organophosphates, Siloxanes, Dopants, Total VOC and others

Materials used in robot systems with possible outgassing behaviour to be monitored:

- Lubricants and sealants
- Surface treatments, coatings and paints
- Plastics and elastomers

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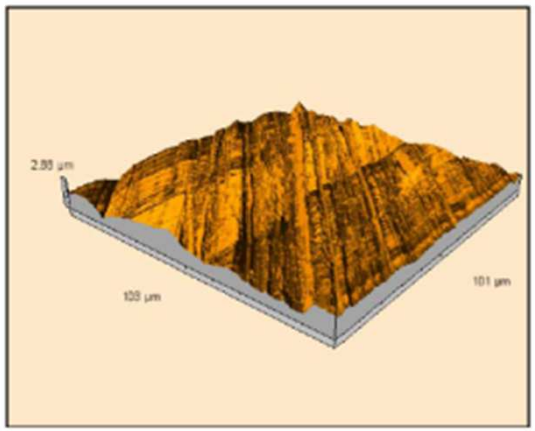
3) Cleanability of Surfaces

Requirements:

- Smooth surfaces with **low surface roughness** value R_a
  ➔ **easy to clean** (e.g. Life-Science industry: R_a < 0,8 µm; ISPE; EHEDG …)
- State-of-the-art measurement systems: SEM, AFM, …

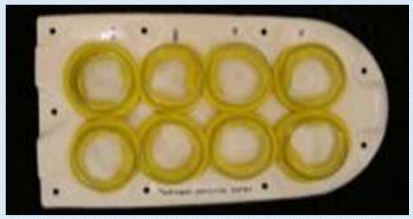
Technical Surface	Surface roughness	
	R_a [µm]	R_{max} [µm]
Stainless steel, electropolished	0.40	3.46
Stainless steel, polished (V2A)	0.65	5.61
Polypropylene (PP)	0.02	0.24
Silicon wafer	**0.001**	**0.005**



Source: stainless steel surface, AFM-picture, Fraunhofer IPA

4) Chemical Resistance of equipment/material surfaces

- Materials: resistant against cleaning and disinfectant liquids being used
- Surfaces: flat and even
- **Range of chemicals** (hedge):
  - butyl acetate
  - diethyl ether
  - peracetic acid (1%)
  - hydrochloric acid (5%)
  - aceton (100%)
  - formalin (37%)
  - hydrogen peroxide (30%)
  - ammonia (25%)
  - ethanol (100%)
  - isopropanol (70%)



Source:
painted robot housing,
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Strategy to improve level of cleanliness

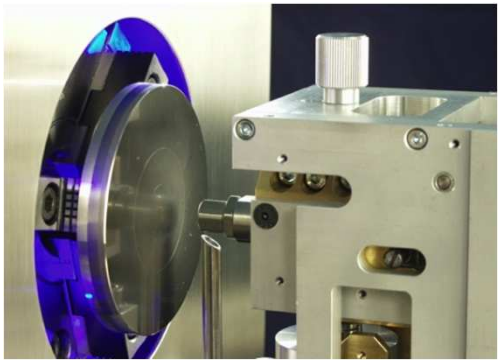
Improvements Strategy

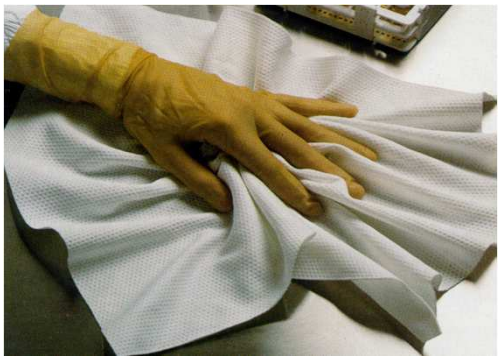
Develop optimization potentials regarding the cleanliness suitability of the robotic arms and end effectors in the following steps:

- inspection of typical systems, subassemblies and production area
- explanations of the systems, subassemblies and production area
- clarification of current problems regarding the manufacture of cleanroom suitable operating utilities, components (selection/mode of operation/layout), devices, equipment, materials and the manufacturing environment
- explanation of possible measures necessary, handling requirements and solutions

Factors influencing cleanliness suitability
Cleanliness-suitable equipment design

Materials used ▶ Design ▶ Cleanliness-suitable assembly





- **Particles**
- **Outgassing behavior**
- **Electrostatic properties**
- **Cleanability**
- **Chemical resistance**
- **Ability to resist metabolism**
- **Toxicity**

Material properties relevant for:

- semiconductor industry
- life science industry

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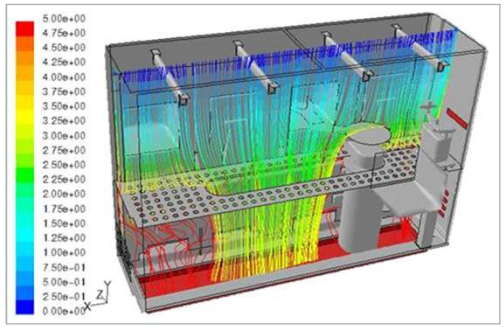
Factors influencing cleanroom suitability
Cleanliness suitable equipment design

Materials utilized ▶ **Design** ▶ Cleanliness-suitable assembly



Construction of wafer handling system

Encapulation of operator and product

Airflow guidance

- Product constantly **subjected to flow of clean air**, **perforated** surfaces, **airflow-optimized shapes** for closed surfaces (e.g. »teardrop lights«)
- Active airflow **guidance**, e.g. shadowing of operator/sources of contamination using static positive pressure

Constructional measures

- Minimize **friction** processes; **surface** quality
- **Placement** of sources of contamination: downstream of product or in outer area
- **Encapsulation** or use of a vacuum (extraction)

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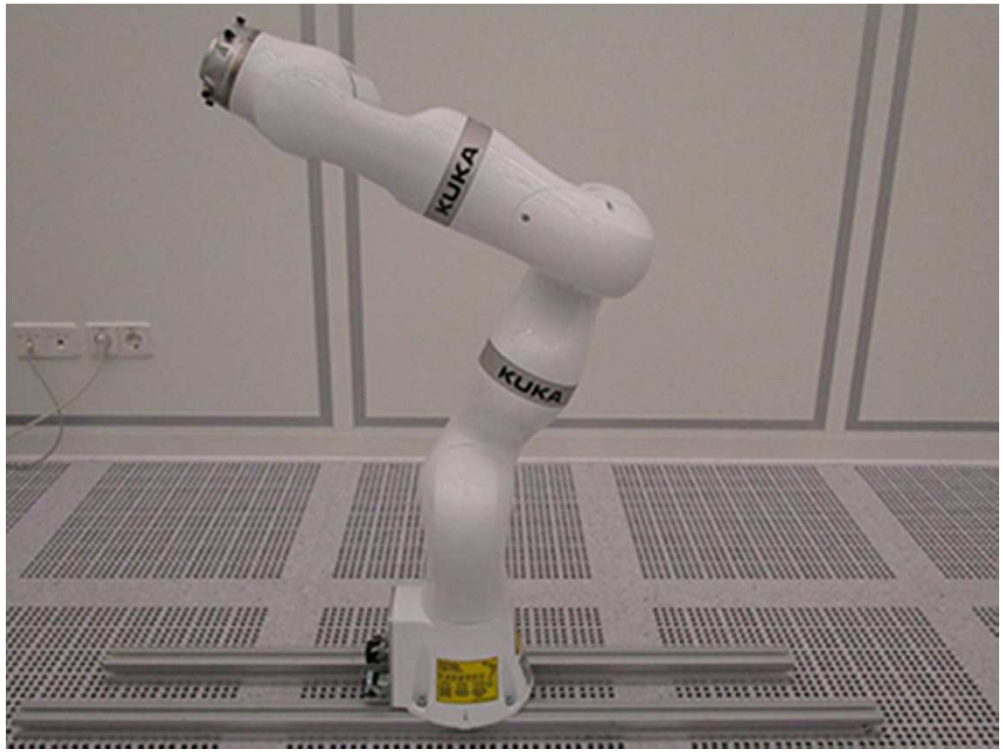
Factors influencing cleanroom suitability
Cleanliness suitable equipment design

Materials utilized ▶ Design ▶ **Cleanliness-suitable assembly**

Assembly

- Under cleanroom conditions
- Protective clothing and restricted personnel behavior
- Tools, workplaces must be kept clean
- Single components to be cleaned before being assembled
- Assembly (e.g. joining) might be contaminating
- Final cleaning of products
- Avoid rework
- Cleanliness optimized packaging and transport

KUKA LBR IIWA 7 R800/R820



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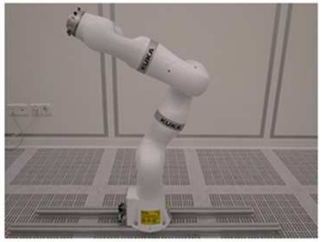
Current Cleanliness Status: KUKA LBR IIWA 7 R800/R820

Search ▶ Last Search ▶ LBR iiwa 7 R800 CR (prototype 2) / workload: 7 kg / range: 800 mm



Company

KUKA Roboter GmbH

Zugspitzstrasse 140

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Contact Person

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Test Object

	LBR iiwa 7 R800 CR (prototype 2) workload: 7 kg range: 800 mm
Q-Id	KU 1506-769
Year	2015
Comments	Manufacturing date: 29/05/2015 | mit Blindstecker und versiegelten Spalten
Category	Robotics

Tests And Results

Subject of Test	Parameter	Assessment for / Results	Documents (valid to)
Particle emission (VDI 2083 part 9.1)	Moving axis: 1-7 Capacity: 40 % Attached payload: 7 kg Vacuum suction: 7 m³/h Axis 1: -150 - 150 ° Axis 2: -70 - 70 ° Axis 3: -165 - 165 ° Axis 4: -70 - 70 ° Axis 5: -165 - 165 ° Axis 6: -70 - 70 ° Axis 7: -170 - 170 °	ISO 14644-1 / ISO Class 3 US FED 209E / US Class 1	certificate 1 de (18-11-20) certificate 1 en (18-11-20) statement 1 de (18-11-20) statement 1 en (18-11-20)
	Moving axis: 1-7 Capacity: 80 % Attached payload: 7 kg Vacuum suction: 7 m³/h Axis 1: -150 - 150 ° Axis 2: -70 - 70 ° Axis 3: -165 - 165 ° Axis 4: -70 - 70 ° Axis 5: -165 - 165 ° Axis 6: -70 - 70 ° Axis 7: -170 - 170 °	ISO 14644-1 / ISO Class 2 US FED 209E / US Class 1	

➔ between ISO Class 2 to 3

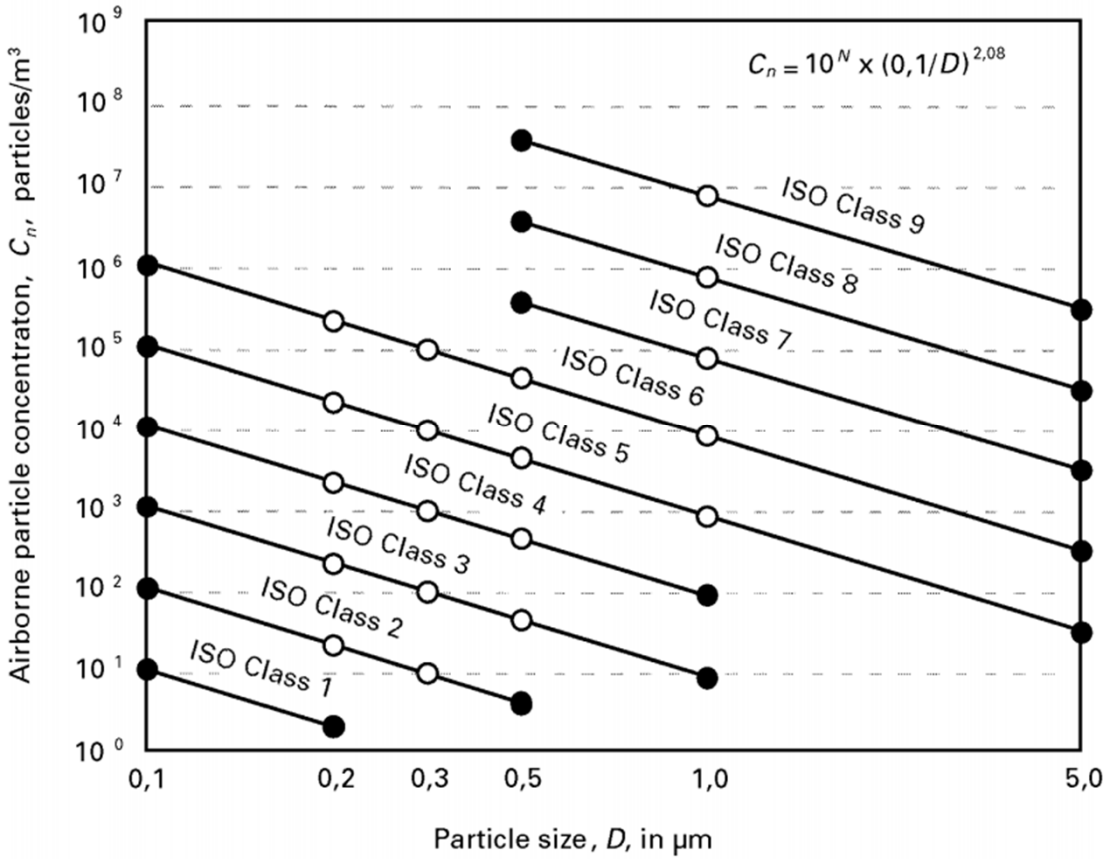
http://www.db.cleanmanufacturing.fraunhofer.de/en/web/guest/qdb/-/ipa-cmqd-search/show?_search_WAR_managecontacts_unitUnderTestId=1706&_search_WAR_managecontacts_categoryId=0&_search_WAR_managecontacts_worstIsoClass=&_search_WAR_managecontacts_year=0&_search_WAR_managecontacts_search=kuka+lbr&_search_WAR_managecontacts_subjectOfTest=%25&_search_WAR_managecontacts_orderBy=sortingWorstIsoClass&_search_WAR_managecontacts_currentPage=1

Annex

1) Airborne Particle Cleanliness acc. to 14644-1 and WG11

- Particle concentration within air volume of 1 m³
  ➔ cleanroom classification
  (acc. to 14644-1)

- Particle concentration on single point of an equipment, "emitted into" air volume of 1 m³
  ➔ equipment classification
  (acc. to WG11-approach)



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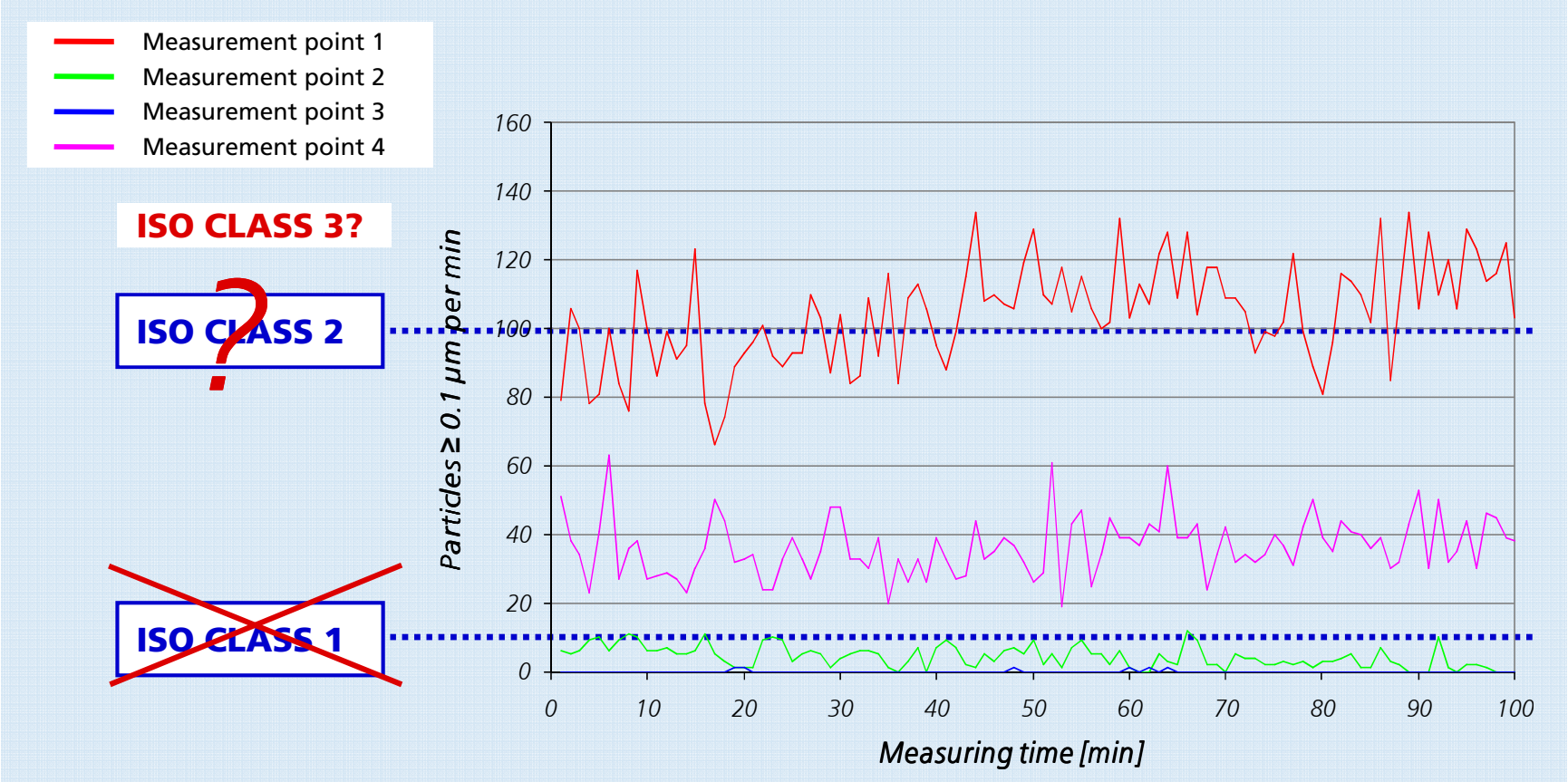
1) Particle Emission Test of a Robot System – Interpretation of Measurement Values



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1) Particle Emission Test of a Robot System – Statistical Analysis (as Example on MP1)

Determination of **probability** to exceed particle class limits

- at single measurement points
- in acc. to class limits of ISO 14644-1 (or any other air cleanliness standard)
- classification with Poisson- and Student-t-statistics

Statistical parameters		Measurement Points			
		MP1	MP2	MP3	MP4
Mean values for the detection size [particles / cft]	0.2 µm	51.7	0.0	3.2	0.0
	0.3 µm	20.1	0.0	1.3	0.0
	0.5 µm	3.5	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0	0.0
Standard deviation for the detection size [particles / cft]	0.2 µm	19.3	0.2	2.3	0.2
	0.3 µm	13.7	0.2	1.4	0.1
	0.5 µm	2.9	0.2	0.0	0.0
	5.0 µm	0.0	0.0	0.0	0.0
Air Cleanliness Class [ISO 14644-1]		4	1	3	1
Limiting values of particles in corresponding air cleanliness class for the detection size [particles / cft]	0.2 µm	67	0.0	7	0.0
	0.3 µm	29	0.0	3	0.0
	0.5 µm	10	0.0	1	0.0
	5.0 µm	0.0	0.0	0.0	0.0
Probability of exceeding limiting values for the detection size [%]	0.2 µm	<0.1	3.0	1.7	3.0
	0.3 µm	<0.1	3.0	4.5	1.0
	0.5 µm	<0.1	3.0	<0.1	<0.1
	5.0 µm	<0.1	<0.1	<0.1	<0.1
Statistical certainty of keeping within the required limiting value for the given air cleanliness class [%]		>99.9	97.0	95.5	97.0

1) Particle Emission Test of a Robot System
Overview: Air Cleanliness Classes

Regulatory				Limiting values of each Air Cleanliness Class for differing particle sizes and reference volumes (according to ISO 14644-1)											
ISO 14644-1	EU-GMP „at rest“	EU-GMP „in operation“	US Fed. Standard 209E*	0.1 µm		0.2 µm		0.3 µm		0.5 µm		1.0 µm		5.0 µm	
				per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf
1				10	0,3	2	0,1								
2				100	3	24	1	10	0,3	4	0,1				
3				1.000	30	237	7	102	3	35	1	8	0,2		
			1	1.240	35	265	8	106	3	35	1				
4				10.000	300	2.370	67	1.020	29	352	9,9	83	2		
			10	12.000	340	2.650	75	1.060	29	353	10				
5				100.000	2.833	23.700	671	10.200	286	3.520	100	832	24	29	0,8
	A									3.520	100			20	0,6
		A								3.520	100			20	0,6
	B									3.520	100			29	0,8
			100			26.500	750	10.600	300	3.530	100				
6				1.000.000	28.329	237.000	6.710	102.000	2.890	35.200	977	8.320	235	293	8
			1.000							35.300	1.000			247	7
7										352.000	9.972	83.200	2.357	2.930	83
	C									352.000	9.972			2.900	82
		B								352.000	9.972			2.900	82
			10.000							353.000	10.000			2.470	70
8										3.520.000	99.716	832.000	23.569	29.300	830
	D									3.520.000	99.716			29.000	821
		C								3.520.000	99.716			29.000	821
			100.000							3.530.000	100.000			24.700	700
9										35.200.000	997.167	8.320.000	235.694	293.000	8.300

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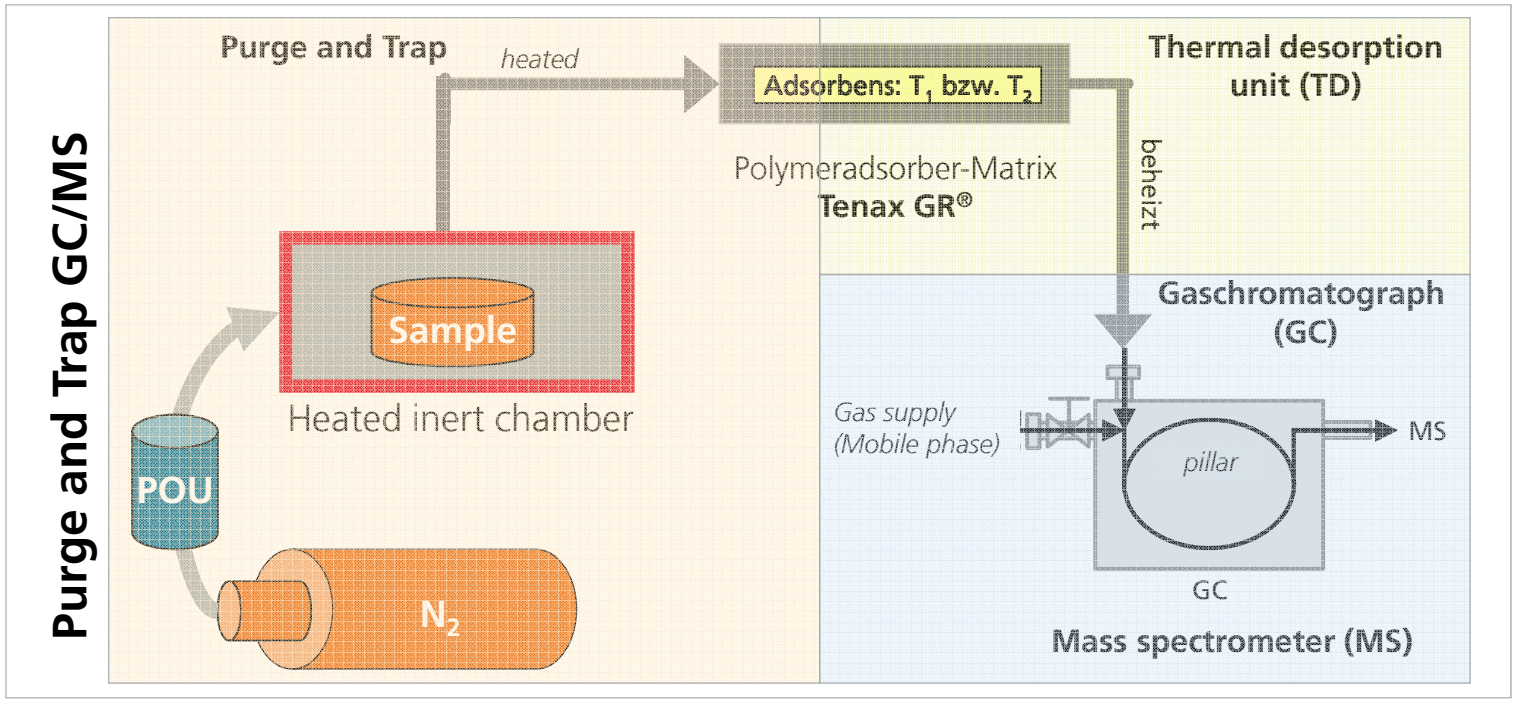
2) Outgassing behaviour – Measurement Technique

- Defined set of parameters:
  sample size, material, assessment time after production, purge time, temperature, change of air volume, etc.



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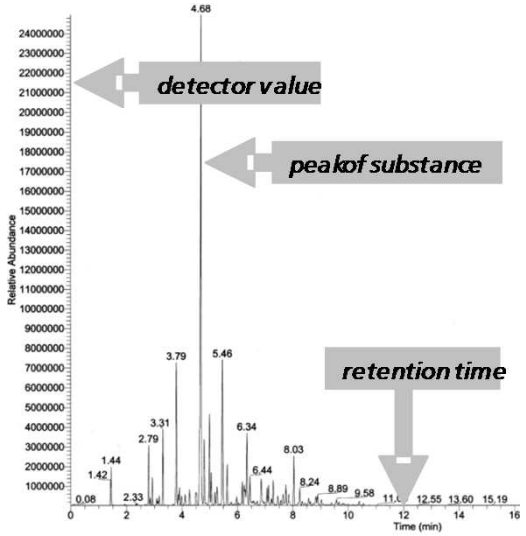
2) Outgassing behaviour – Assessment

- **Qualitative** measurements: which substances
- **Quantitative** measurements:
  mass of outgassing substances
  Single substances (VOC) & Total quantity (TVOC)
- New: mass of outgassing substances correlated **to »active« surface area of the sample**
  in µg/m² (until now: µg/g, µg/m³)



- Basis of classification = outgassing-mass, »emitted into« air volume of 1 m³
  ➔ concentration in g/m³
- Classification acc. to ISO 14644-8, e.g. TVOC (23 °C), **ISO class $_{[acc]}$ –5**

ISO-AMC Class	0	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11	-12
Concentration [g/m³]	10^{0}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	10^{-10}	10^{-11}	10^{-12}

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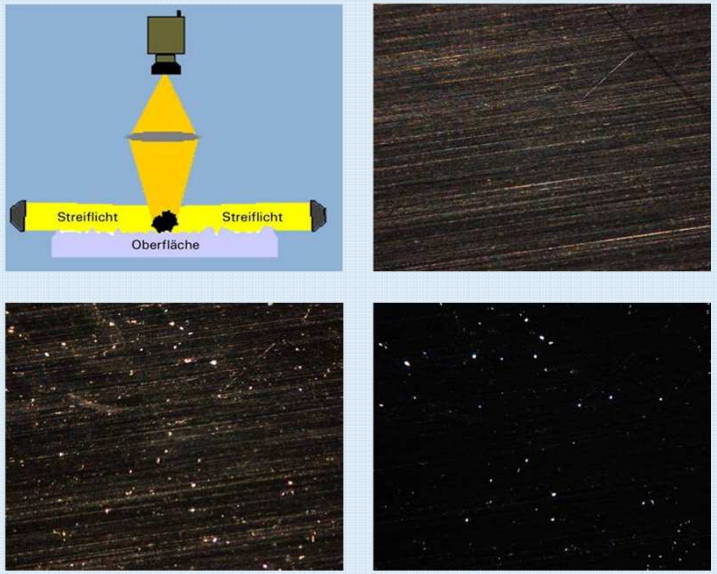
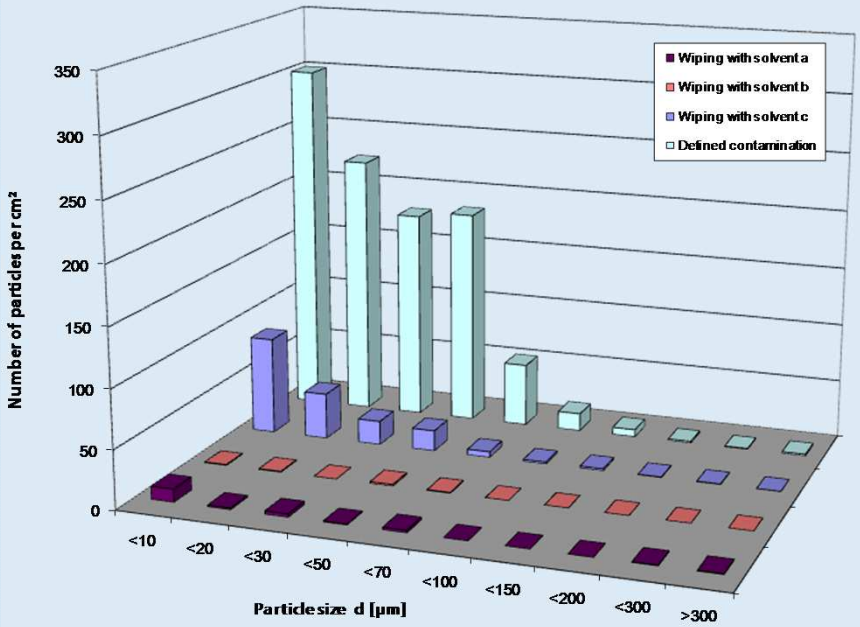
3) Cleanability of Surfaces; – Measurement Technique

- Comparison of different cleaning detergents regarding particle reduction on equipment surface



Adapted Measurement Technique



Particle Residues on Surface

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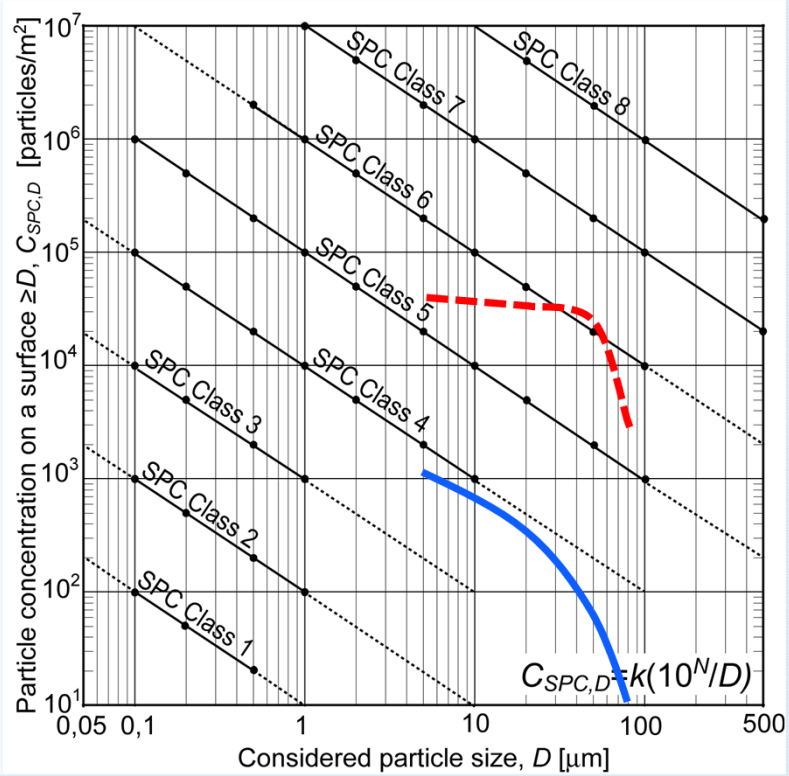
3) Cleanability of Surfaces – Assessment



Assessment of **surface cleanliness levels** acc. to ISO 14644-9

Detected particle size [µm]	*Mean particle concentration **BEFORE** cleaning [particle / cm²]*	*Mean particle concentration **AFTER** cleaning [particle / cm²]*	***Cleaning efficacy** per detected particle size*
≥ 5	*41677*	*1142*	*97,26%*
≥ 20	*39639*	*384*	*99,03%*
≥ 50	*23042*	*65*	*99,72%*
≥ 80	*4417*	*11*	*99,75%*
	***Cleaning efficacy** (mean value)*		***98,94%***

Detected particle size [µm]	*SPC-class **BEFORE** cleaning*	*SPC-class **AFTER** cleaning*	***SPC-cleaning efficacy***
≥ 5	*6*	*4*	***2***
≥ 20	*6*	*4*	***2***
≥ 50	*7*	*4*	***3***
≥ 80	*6*	*3*	***3***

SCP-Cleaning Efficacies acc. to ISO 14644-9

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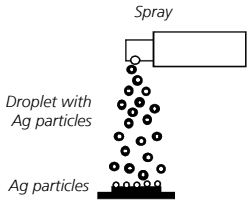
3) Cleanability of Surfaces – Method to determine the »Cleaning Efficacy«

Efficiency regarding removal of particles:



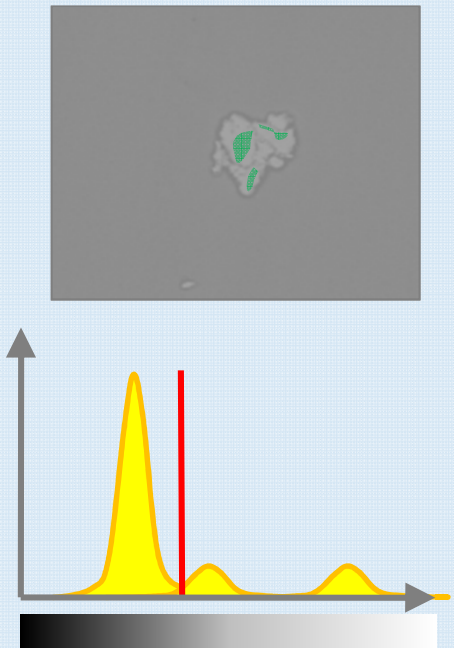
Procedure:

- **Defined contamination** of test pieces with silver particles 0.5µm and larger
- Autom. full-surface SEM **particle count**
- Automated **cleaning** with specific cleaning technology
- **Renewed count** and determination of **cleaning efficiency**

	Particle size		
	1-5µm	5-10µm	10-50µm
Before	47023	9427	3063
After	66	0	0
Efficiency	46957	9427	3062
Efficiency %	99.9%	100%	100%

Requirement:

Adequate **material contrast** between particles and surface



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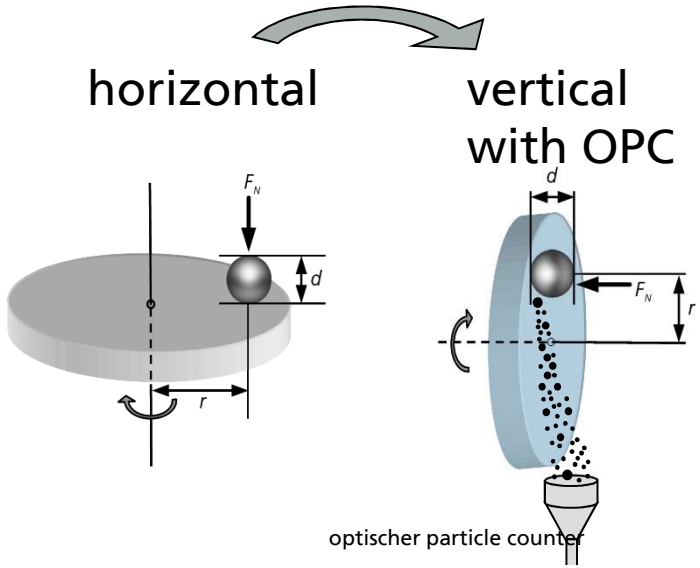
1) Measurement Procedure to classify Materials (for its particle behaviour)

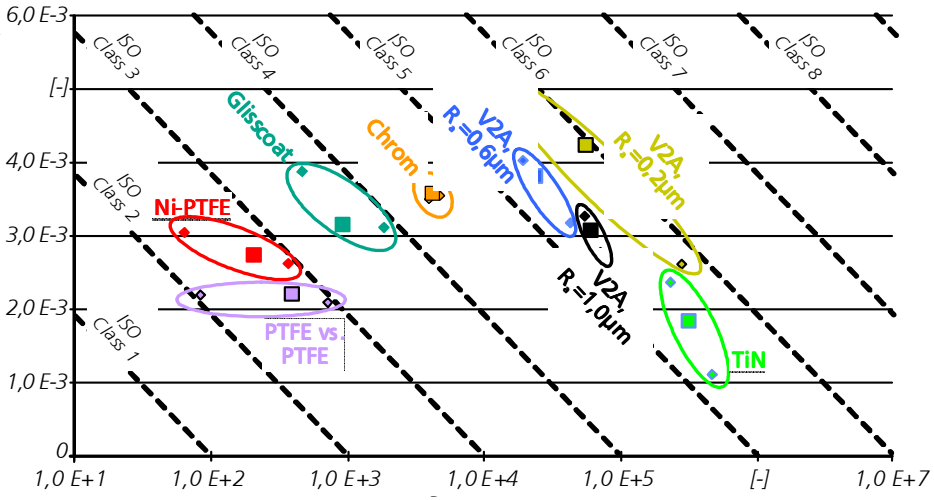
Creative approach for test bench development:

- ➔ Model tests according to established ball & disk test technique from the field of tribology
- ➔ Turning the test arrangement
- ➔ Simultaneous measurement of emitted particles using an optical particle counter

Analysis of the data

- ➔ Procedure enables clear classification of cleanroom suitability of materials





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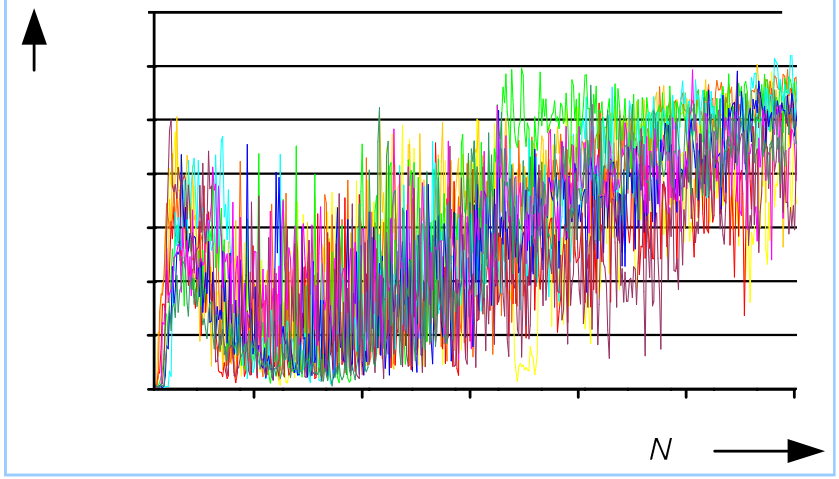
1) Measurement Procedure to classify Materials (for it's particle behaviour)

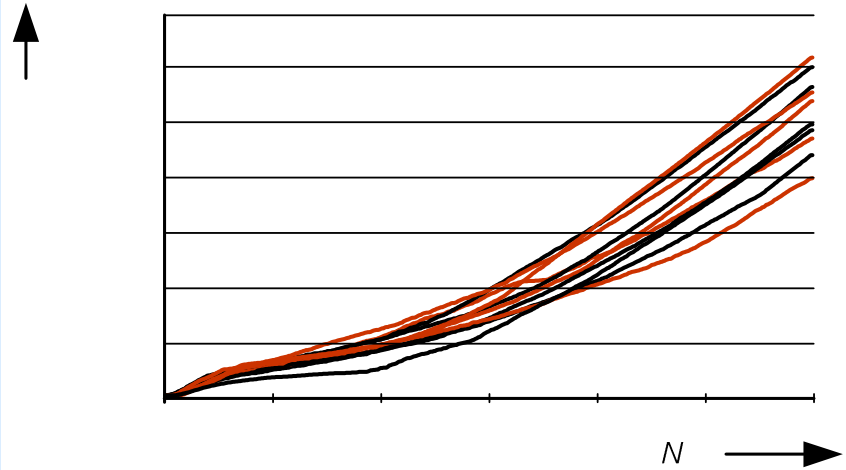
Example of a typical tribosystem

material pairing = metallic reference samples: V2A ↔ 100Cr6

Measurement data recorded for V2A ↔ 100Cr6



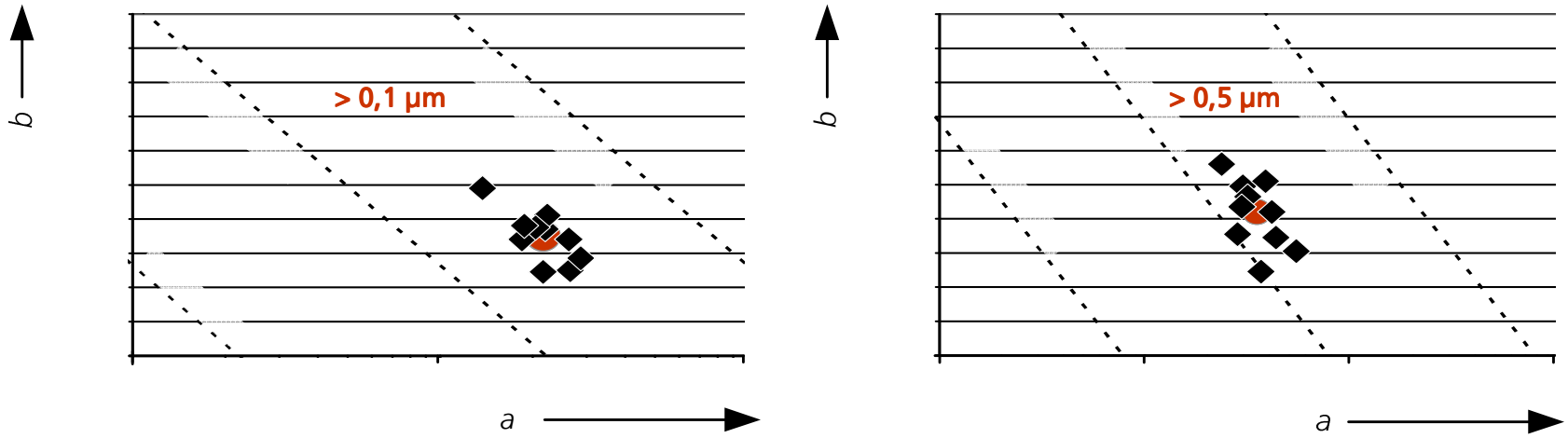
Differential representation;
Only tendencies recognizable



Cumulative representation;
Exponential progression recognizable

1) Measurement Procedure to classify Materials (for it's particle behaviour)

Dependence on particle size



V2A ↔ 100Cr6

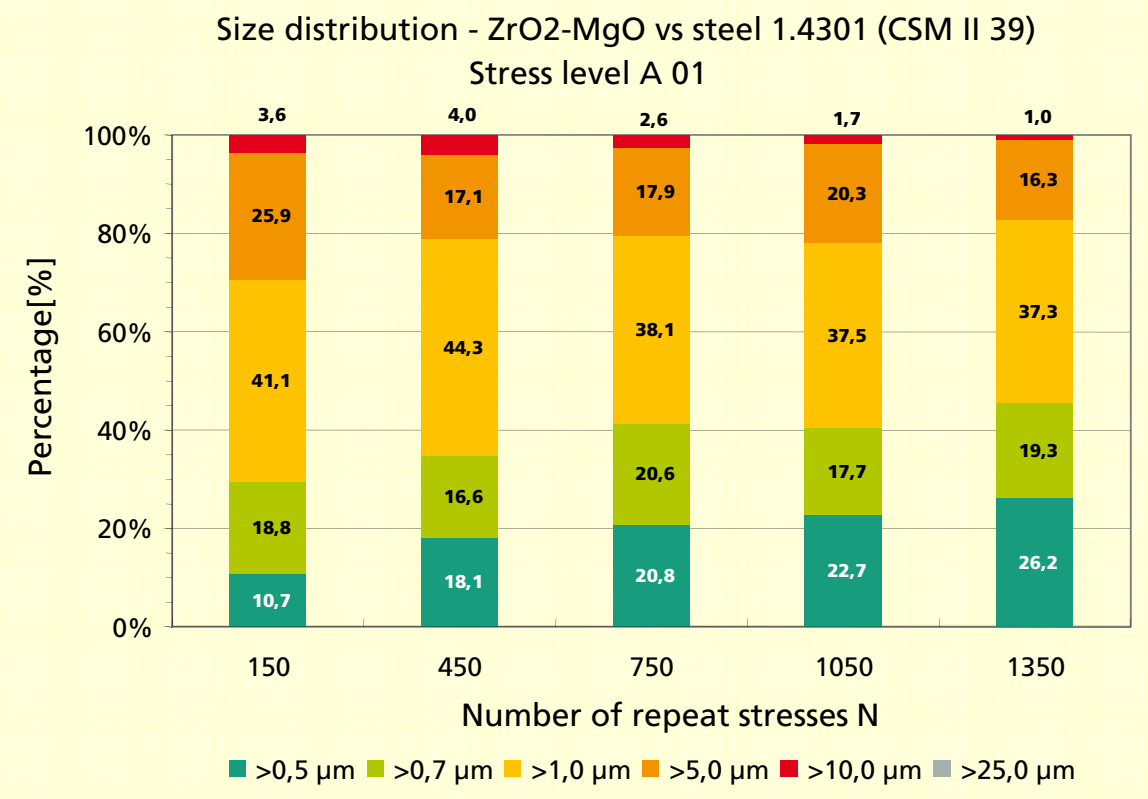
◆ Single measurement value recording

● Mean of single measurement value recordings

Assessment differentiates between varying particle sizes

1) Measurement Procedure to classify Materials (for it's particle behaviour)

Time-dependent development of particle size



Method provides information about **dynamic wear processes**:

Time-development of

- particle sizes
- cleanroom classification
- friction coefficients
- force patterns
- degree of wear

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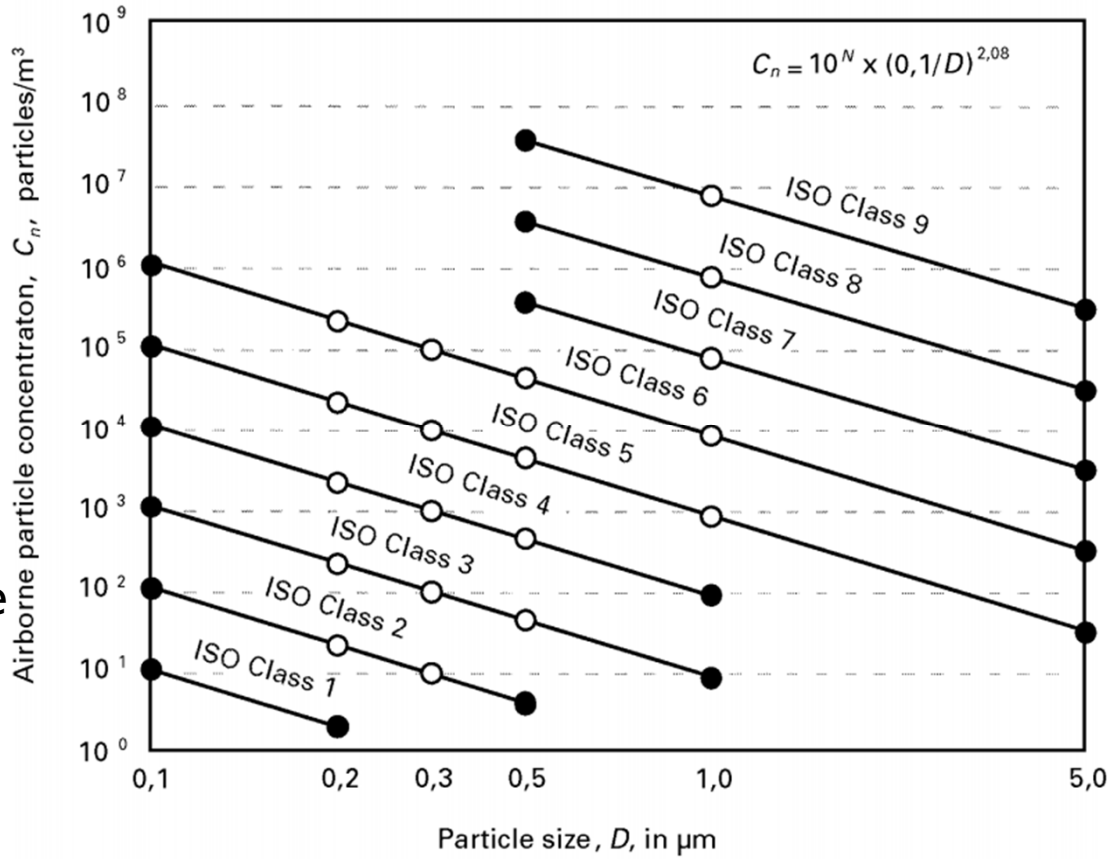
1) Measurement Procedure to classify Materials (for it's particle behaviour)

- Particle concentration "within" air volume of 1 m³
  ➔ cleanroom classification
  (acc. to 14644-1)

- Particle concentration on single point of an equipment/material, "emitted into" air volume of 1 m³
  ➔ equipment/material classification
  (acc. to ISO/CD 14644-14)



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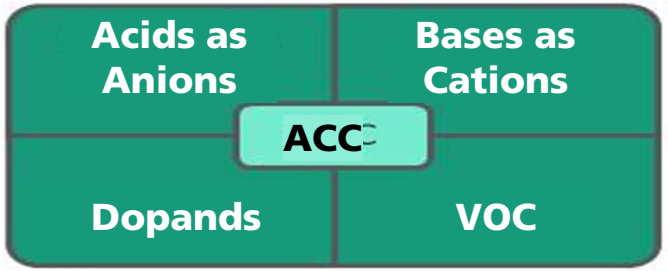
2) Outgassing behaviour of Equipment-Materials used

To find out about the **suitability of equipments** to be used in **ACC-controlled environments:**
➔ outgassing of materials have to be determined

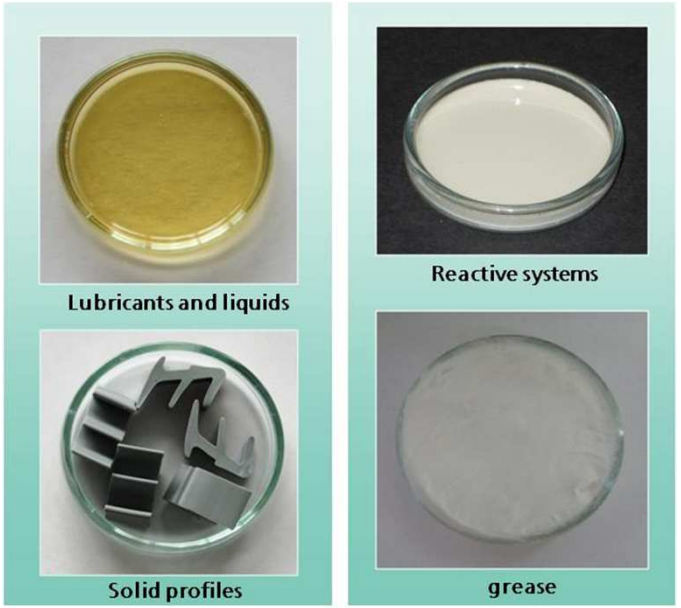


(SEMI F21-95; Gail, 2002)

Critical components for clean applications:
Amines, Phthalates, Organophosphates, Siloxanes, Dopants, Total VOC and others

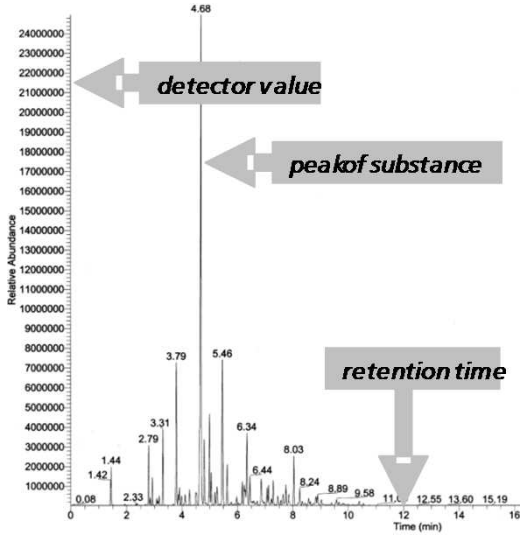
Materials used in equipment with potential ACC emission to be monitored:

- Lubricants and sealants
- Surface treatments, coatings and paints
- Plastics and elastomers



2) Outgassing behaviour of used Equipment Materials - Assessment

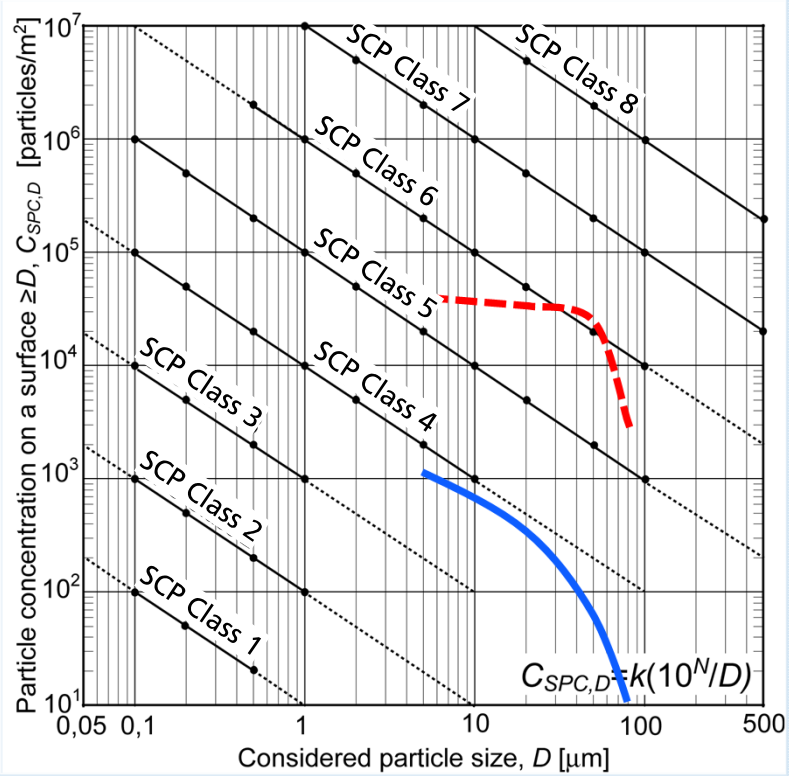
- **Qualitative** measurements: which substances
- **Quantitative** measurements:
  mass of outgassing substances
  Single substances (VOC) & Total quantity (TVOC)
- New: mass of outgassing substances correlated **to »active« surface area of the sample**
  in µg/m² (until now: µg/g, µg/m³)



- Basis of classification = outgassing-mass, »emitted into« air volume of 1 m³
  ➔ concentration in g/m³
- Classification acc. to ISO 14644-8, e.g. TVOC (23 °C), **ISO class $_{[acc]}$ –5**

ISO-AMC Class	0	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11	-12
Concentration [g/m³]	10^{0}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	10^{-10}	10^{-11}	10^{-12}

3) Cleanability of Surfaces - Assessment



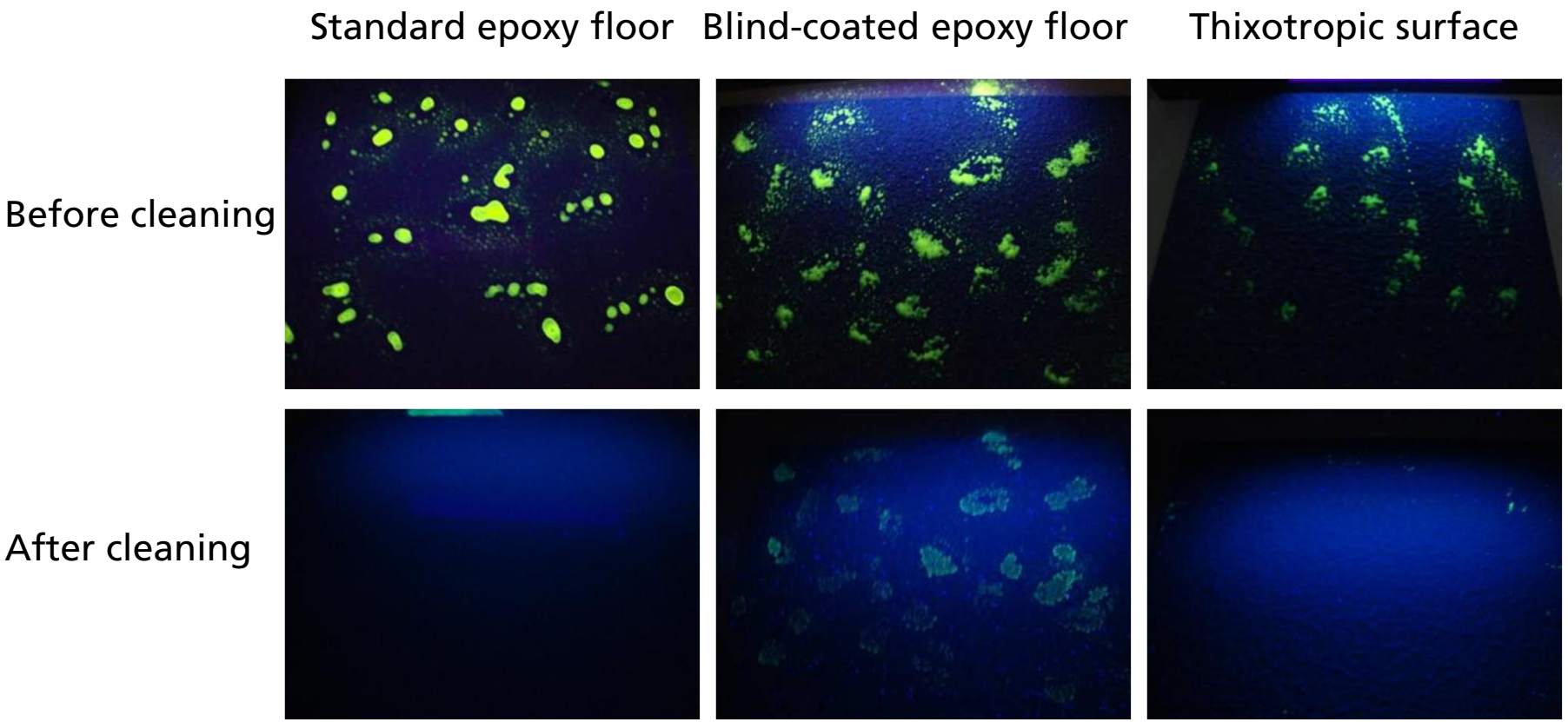
Assessment of **surface cleanliness levels** acc. to ISO 14644-9

Detected particle size [µm]	*Mean particle concentration **BEFORE** cleaning [particle / cm²]*	*Mean particle concentration **AFTER** cleaning [particle / cm²]*	***Cleaning efficacy** per detected particle size*
≥ 5	41677	1142	97,26%
≥ 20	39639	384	99,03%
≥ 50	23042	65	99,72%
≥ 80	4417	11	99,75%
	***Cleaning efficacy** (mean value)*		**98,94%**

Detected particle size [µm]	*SCP-class **BEFORE** cleaning*	*SCP-class **AFTER** cleaning*	***SCP-cleaning efficacy***
≥ 5	6	4	**2**
≥ 20	6	4	**2**
≥ 50	7	4	**3**
≥ 80	6	3	**3**

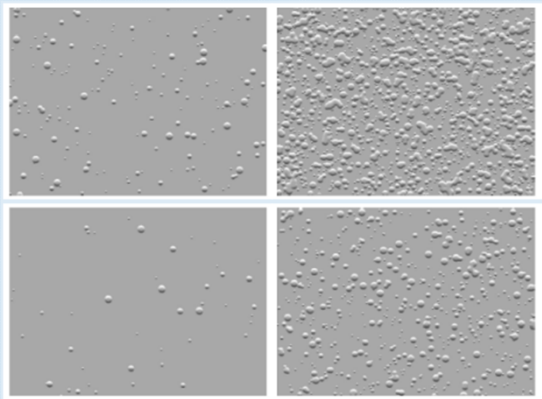
SCP-Cleaning Efficacies acc. to ISO 14644-9

3) Cleanability of Surfaces
- VDMA riboflavin test for qualitative assessment



4) Chemical Resistance of equipment/material surfaces

- Materials: resistant against cleaning and disinfectant liquids being used
- **Range of chemicals** (hedge):
  - butyl acetate
  - diethyl ether
  - peracetic acid (1%)
  - hydrochloric acid (5%)
  - aceton (100%)
  - formalin (37%)
  - hydrogen peroxide (30%)
  - ammonia (25%)
  - ethanol (100%)
  - isopropanol (70%)
- Tests are performed according to ISO 2812-1: submers-method
- Classification according to ISO 4628: Assessment of visible surface change/damage

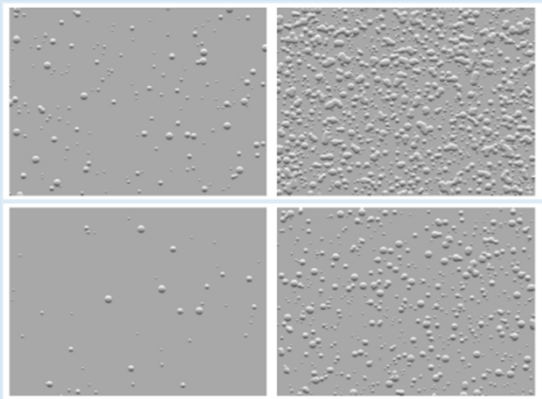


Value	Scale of Assessment	Assessment
0	No alteration	RESISTANT
1	Traces of alteration	PARTIALLY RESISTANT
2	Slight alteration	
3	Average alteration	NOT RESISTANT
4	Severe alteration	
5	Extreme alteration	

4) Chemical Resistance of equipment/material surfaces – Assessment

Resistance against chemicals/cleaning detergents:

- Used materials have to be resistant against cleaning and disinfection detergents.
- For wide range to cover: intended use of specimen and a **selection of chemicals** to be tested



Value	Scale of Assessment	Assessment
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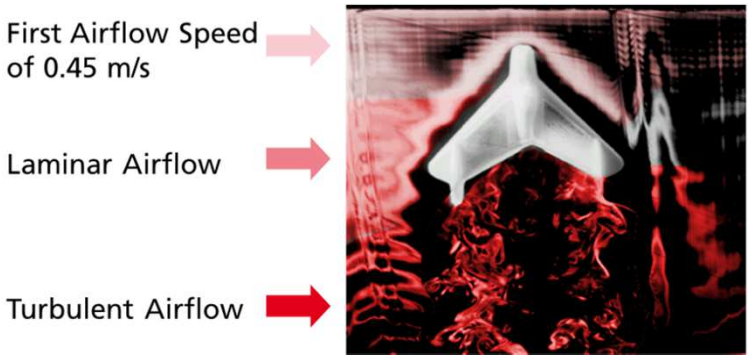
1	Traces of alteration	PARTIALLY RESISTANT
2	Slight alteration	
3	Average alteration	NOT RESISTANT
4	Severe alteration	
5	Extreme alteration	

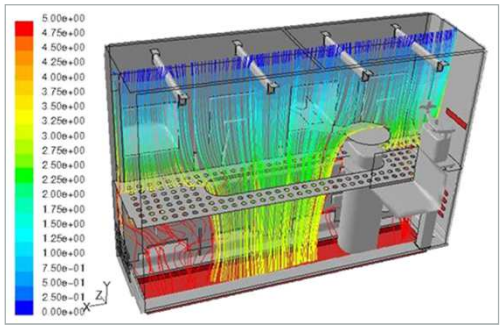
Tests are performed according to:

- ISO 2812-1: submers-method
- Classification according to ISO 4628-1
- Assessment of the visible surface change and damage

5) Airflow visualization of robotic arms

- The airflow is an important parameter influencing the number of particles in the vicinity of products. Any airborne particles generated are invariably transported by the airflow.
- With the aid of airflow visualization or simulation, information can be gained regarding airflow patterns of robotic arms and in the direct surroundings of the arm.
- Dead water and areas of turbulence may occur. Different airflow directions exist within these areas which may oppose the airflow in the surrounding. Particles within these areas may then not be effectively removed by the airflow. By way of airflow tests, information can be obtained concerning the airflow properties of the system which may have a potential influence on particle deposition and cross-contamination.
- The airflow of the complete system is visualized using a fog generator based on the contamination-free nebulization of DI water. The fog is dispensed above the area of investigation. With the aid of video recordings and photos, localized and general airflow patterns are documented and analyzed.
- The airflow of the complete system can be simulated using CFD software (Fluent of ANSYS, Inc.).





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6) Hygienic Design

Expert reports are carried out at the Fraunhofer IPA as a means of proving good manufacturing practices as required by GMP guidelines. The aim of the expertises is to confirm and document the suitability of operating utilities for use in clean manufacturing areas through independent reports written by scientists. The expertises are compiled taking important norms and guidelines into consideration which are concerned with manufacturing under clean conditions.

Analysis of conception and design

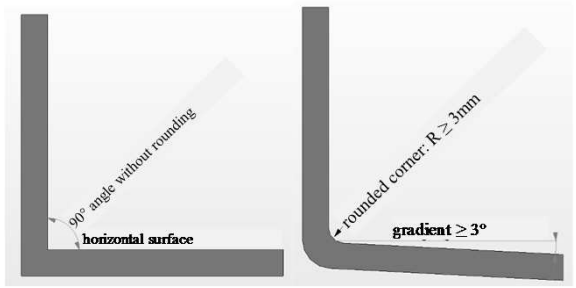
In accordance with the guidelines of the EHEDG (European Hygienic Equipment Design Group) and GMP (Good Manufacturing Practice), the conception and design of robotic arms and quality of workmanship are evaluated. The assessments are made based on expertises made by experts from the Fraunhofer IPA.

The expertises to assess the hygienic design of a test piece evaluate such parameters as:

- Materials used
- Material pairings
- Geometries of materials used
- Joining techniques
- Constructive detail solutions
- Components installed
- Manufacturing techniques
- Surface coatings / coating systems
- etc.

An assessment of the technical implementation and execution of conception and design specifications or recommendations as laid down in EHEDG and GMP guidelines is also carried out.

The customer shall provide Fraunhofer IPA a list of the used materials. The list is necessary to perform an accurate assessment also in view of the used materials.



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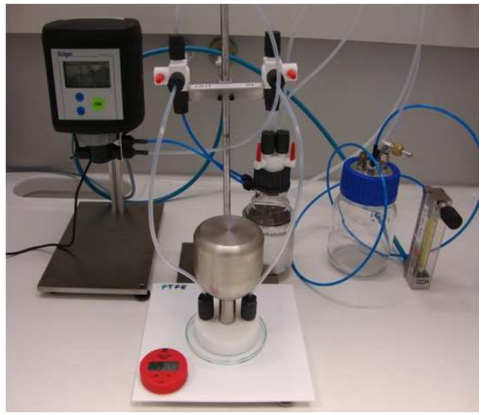
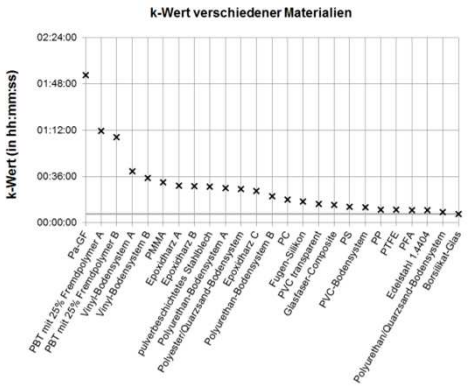
7) H_2O_2 absorption/desorption

- Environments for sterile production require regular decontamination in order to minimize the biological burden to an accepted level. Nowadays, the usage of vaporized hydrogen peroxide to decontaminate controlled environments (e.g. isolators) is the preferred method because this has several advantages over other decontamination procedures and decontaminating agents.
- Each decontamination cycle ends with an aeration phase in order to reduce the vaporized hydrogen peroxide concentration to a specified limit. In addition to process-controlled parameters, e.g. rate of air-exchange in the room, the aeration time is also influenced by the vaporized hydrogen peroxide adsorption /desorption behavior of all exposed materials used in the controlled environment. Therefore, a material assessment will help to select suitable materials with a low adsorption of vaporized hydrogen peroxide and its fast desorption during aeriation.
- The material sample is placed into an emission cell. The duration of the exposure with vaporized hydrogen peroxide with a defined standardized concentration is one hour. After one hour, the setup is changed into aeration mode. The continuous monitoring of the vaporized hydrogen peroxide concentration enables the calculation of a k-value regarding the desorption kinetic of vaporized hydrogen peroxide. Possible catalytic activity of a material can be detected during the adsorption phase of the measurement. All measurements will be performed as triplicate using a fully standardized method to enhance the validity of the results.





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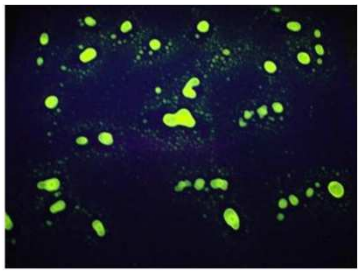
8) Riboflavin test to assess cleanability

Before Cleaning

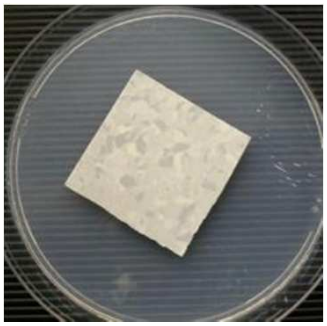


After Cleaning

The procedure is based on the riboflavin test of the German Engineering Federation (VDMA) as of 12/2007. The aim of the test is to provide qualitative proof of the ability to reduce fluorescing test contamination using the representative cleaning method selected. To do this, fluorescing test contamination is first prepared and subsequently applied to the test piece. The advantage of fluorescing test contamination is that very small quantities can be detected and also that excellent locally-resolved photographic material can be obtained. The test contamination is left to dry on for a period of 2 hours and then cleaned off using a wiping simulator. After cleaning, any remaining residual contamination is then identified through fluorescent excitation and documented by way of detailed photography. To achieve adequate statistical certainty, three repeat tests are carried out. The tests are evaluated according to ISO 4628-2 “Evaluation of degradation of coatings”, which assesses the size and quantity of fluorescing residues. Results are then classified in accordance with VDI 2083-17.

9) Biological resistance

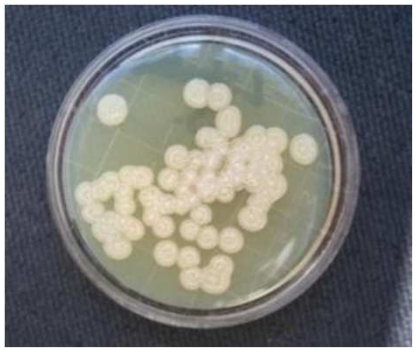
- test method according to ISO 846
  Method A: fungi
  Method C: bacteria
- incubation of test samples (approx. 50 x 50 mm) with appropriate inoculum placed on a carbon-free agar-media
- visual and microscopic growth inspection after incubation for 4 weeks at 24 °C for fungi and bacteria
- CSM-Classification is the inferior value of the biological resistance results of method A and method C



Biological resistance	CSM-Classification	Assessment
0	excellent	not visible by 10x magnification
1	very good	only visible by 10x magnification
2	good	visible by normal eyesight, up to 25 of sample surface covered
3	weak	visible by normal eyesight, up to 50 % of sample surface covered
4	very weak	considerable growth, over 50 % of sample surface covered
5	none	strong growth, whole sample surface covered

10) Microbicidity

- test method according to ISO 22196
- incubation of test sample with antibacterial property and blank sample of the same material but without antibacterial property
- covering with appropriate lid
- incubation for 24 hours at 35 °C
- recovery of the bacteria from the test samples and determination of the CFU (colony forming units).
- calculation of the R-value
- final CSM-Classification is the achieved R-value after 24 hours incubation



Mikrobicidity R-value	CSM-classification
>= 4	excellent
< 4	very good
< 3	good
< 2	weak
<1	very weak
0	none