

4.6 Qualification measurements

4.6.1 Procedure

The qualification tests were performed according to ISO 14644-14.

Measuring probes were placed at each of the critical sites identified (= measuring points). At each measuring point, particle emission measurements were recorded with measuring intervals of 1/min over a period of 100 minutes. To better compare results, up to 4 particle counters were used in parallel at up to 4 different measuring points for each test series to record particle emission values.

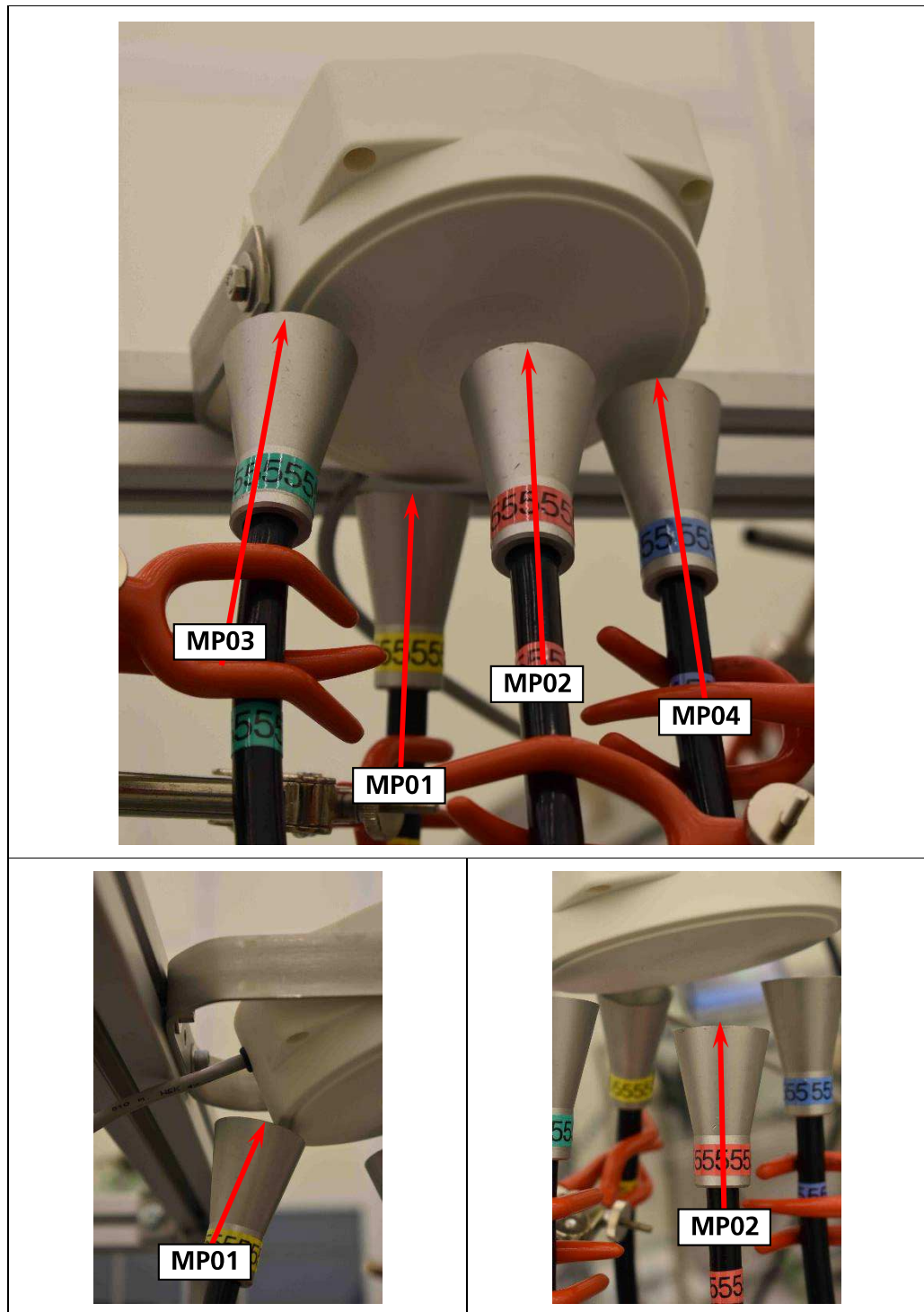
The measurement volume is sucked in at a rate of 1 cft/min. Particle measurements are shown cumulatively for each particle size channel, i.e. the figure shown for a particle size channel refers to all particles equal to or larger than the particle size channel stated ($\geq 0.1 \mu\text{m}$, $\geq 0.2 \mu\text{m}$, $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, $\geq 1.0 \mu\text{m}$ or $\geq 5.0 \mu\text{m}$).

The selected time of 100 minutes ensures adequate statistical certainty of the test results and safeguards against faulty measurements. Each measurement value contains information about the particle size, the quantity of particles generated and the site where the particles were emitted.

The results were analyzed statistically conform to the procedure described in the guideline ISO 14644-14, thus enabling the suitability of the operating utility for use in cleanrooms classified according to ISO 14644-1 to be determined.

4.6.2 Description of the measuring points MP01 to MP04

The following photographs show the exact points selected to measure airborne particles emitted from the test piece.



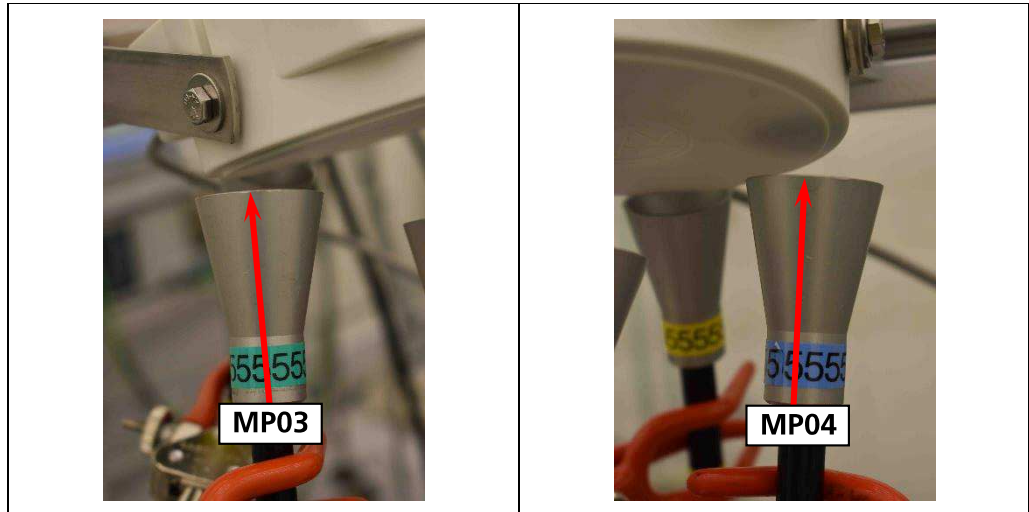


Figure 5

Measuring points MP01 to MP04 selected to measure airborne particle emissions from TP01

4.6.3 Analysis of the results from the airborne particle emission tests

The emission tests mentioned in Chapter 4.6.1 were analyzed according to ISO 14644-14. This included:

- The course of particle emissions at each measuring point over time
- Classification of the various measuring points according to ISO 14644-1 with mean and maximum particle emission values

4.6.4 Course of particle emissions over time

The following diagram shows the course of particle emissions at each of the measuring points, as well as for the stated particle size channels, over the total testing time required by the qualification test. The measuring interval of 1 min was the same for all tests. This equates to a test volume of cubic foot (cft).

Occurrence of contamination over time:

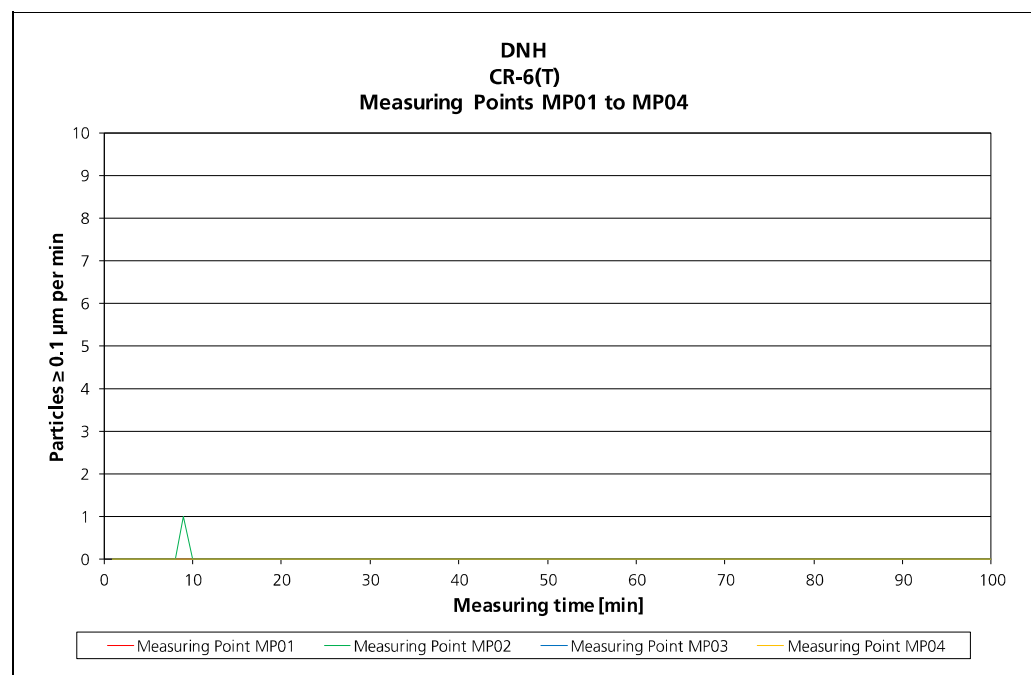


Figure 6

Course of the emission of airborne particles $\geq 0.1 \mu\text{m}$ over time from the test piece at measuring points MP01 to MP04 over the period of 100 minutes

4.7 Classification

The aim of the tests was to ascertain to what extent the test piece may be operated in clean environments. For this, based on the procedure described in the guideline "Assessment of suitability for use of equipment by airborne particle concentration ISO 14644-14", the empirically-calculated measurement values were analyzed statistically and assessed according to the class limits stated in ISO 14644-1.

4.7.1 Statistical verification of the test results

International standards defining air cleanliness, such as ISO 14644-1, state limit values for the air cleanliness classes that are defined in the respective norm. These limit values are set for a specific number of particle size channels (e.g. $\geq 0.1 \mu\text{m}$, $\geq 0.2 \mu\text{m}$, $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, $\geq 1.0 \mu\text{m}$ and $\geq 5.0 \mu\text{m}$). When comparing empirically-derived values (e.g. from a qualification test) with such limit values, a certain degree of certainty is required by which the limit value may not be exceeded.

When classifying operating utilities, the standard deviation and mean values are calculated from the measurement values obtained. ISO 14644-14 describes a method which correlates these values with the limit values stated in ISO 14644-1. If a test piece is declared suitable for different classes, the assessment of the test piece is based on the highest class (worst-case assumption).

4.7.2 Mean and maximum particle emission values and classification

The following tables show the respective maximum values and arithmetical mean values of particle emissions recorded at the corresponding measuring points (MP) over the total testing time of 100 minutes. The applicable air cleanliness class according to ISO 14644-1 for each measuring point is highlighted.

DNH CR-6(T) Measuring Points MP01 to MP04					
Statistical parameters		Measuring Point			
		MP01	MP02	MP03	MP04
Mean value for the detection size [particles / cft]	0.1 μm	0.0	0.0	0.0	0.0
	0.2 μm	0.0	0.0	0.0	0.0
	0.3 μm	0.0	0.0	0.0	0.0
	0.5 μm	0.0	0.0	0.0	0.0
	1.0 μm	0.0	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]	0.1 μm	0.0	0.1	0.0	0.0
	0.2 μm	0.0	0.0	0.0	0.0
	0.3 μm	0.0	0.0	0.0	0.0
	0.5 μm	0.0	0.0	0.0	0.0
	1.0 μm	0.0	0.0	0.0	0.0
	5.0 μm	0.0	0.0	0.0	0.0
Air Cleanliness Class [ISO 14644-1]		1	1	1	1
Maximum value for the detection size [particles / cft]	0.1 μm	0	1	0	0
	0.2 μm	0	0	0	0
	0.3 μm	0	0	0	0
	0.5 μm	0	0	0	0
	1.0 μm	0	0	0	0
	5.0 μm	0	0	0	0
Minimum value for the detection size [particles / cft]	0.1 μm	0	0	0	0
	0.2 μm	0	0	0	0
	0.3 μm	0	0	0	0
	0.5 μm	0	0	0	0
	1.0 μm	0	0	0	0
	5.0 μm	0	0	0	0

Figure 7

Statistical characteristics of the measuring points MP01 to MP04

From the calculations for the respective relevant detection values, it can be derived that the test piece is suitable for use in cleanrooms of **ISO Class 1** according to ISO 14644-1.

4.8 Summary of the classification results

The following table gives an overview of the classification of the various measuring points MP01 to MP04:

CR-6(T) manufactured by DNH				
Measuring Point	MP01	MP02	MP03	MP04
Air Cleanliness Class (according to ISO 14644-1)	1	1	1	1

Figure 8

Overall classification of the speaker CR-6(T)

When operated under the specified test parameters, the speaker **CR-6(T)** manufactured by **DNH** is suitable for use in cleanrooms of **ISO Class 1** according to ISO 14644-1.

4.9 Annex: comparison of different classifications of airborne particulate contamination

In the following table, the limit values defining air cleanliness classes according to the international standard **ISO 14644-1** are compared with the limit values stated in **EG GMP Guideline** Volume 4 Annex 1 and in the American norm **US Federal Standard 209E** (retracted). The comparison concerns the particle size channels stated explicitly in ISO 14644-1; limit values are stated for the reference volumes of 1 m³ and 1 cft (1 cubic foot = 0.0283 m³).

Regulatory				Limiting values of each Air Cleanliness Class for differing particle sizes and reference volumes (acc. to ISO 14644-1)												
EG-GMP "in operation"	EG-GMP "at rest"	US Fed. Standard 209E*	DIN EN ISO 14644-1	0.1 µm		0.2 µm		0.3 µm		0.5 µm		1.0 µm		5.0 µm		
				per [m ³]	per [cft]	per [m ³]	per [cft]	per [m ³]	per [cft]	per [m ³]	per [cft]	per [m ³]	per [cft]	per [m ³]	per [cft]	
			1	10	0,3											
			2	100	3	24	1	10	0,3							
		1	3	1,000	30	237	7	102	3	35	1					
				1,240	35	265	8	106	3	35	1					
		10	4	10,000	300	2,370	67	1,020	29	352	9,9	83	2			
				12,000	340	2,650	75	1,060	29	353	10					
A	A	100	5	100,000	2,833	23,700	671	10,200	289	3,520	100	832	24			
										3,520	100			20	0,6	
	B										3,520	100			20	0,6
											3,520	100			29	0,8
		1,000	6			26,500	750	10,600	300	3,530	100					
				1,000,000	28,329	237,000	6,710	102,000	2,890	35,200	997	8,320	235	293	8	
										35,300	1,000			247	7	
B	C	10,000	7							352,000	9,972	83,200	2,357	2,930	83	
										352,000	9,972			2,900	82	
										352,000	9,972			2,900	82	
										353,000	10,000			2,470	70	
C	D	100,000	8							3,520,000	99,716	832,000	23,569	29,300	830	
										3,520,000	99,716			29,000	821	
										3,520,000	99,716			29,000	821	
										3,530,000	100,000			24,700	700	
			9							35,200,000	997,167	8,320,000	235,694	293,000	8,300	

Figure 9 Overview of limit values for airborne particles per m³ or cft for the standards ISO 14644-1, EU GMP Guideline Volume 4, Annex 1 and US Federal Standard 209E (retracted)

Although limit values are stated for tests on **biotic** airborne particles in EU GMP Guideline Volume 4, Annex 1, this does not form part of the qualification tests conducted at Fraunhofer IPA. Since all manufacturing environments have their own individual germ spectrum, these tests cannot be conducted in a reference laboratory and therefore need to be performed in the respective manufacturing environment. The individual germ spectrum and magnitude of microbial loads are decisively influenced by the production processes, the environment and operating staff in the relevant production areas.