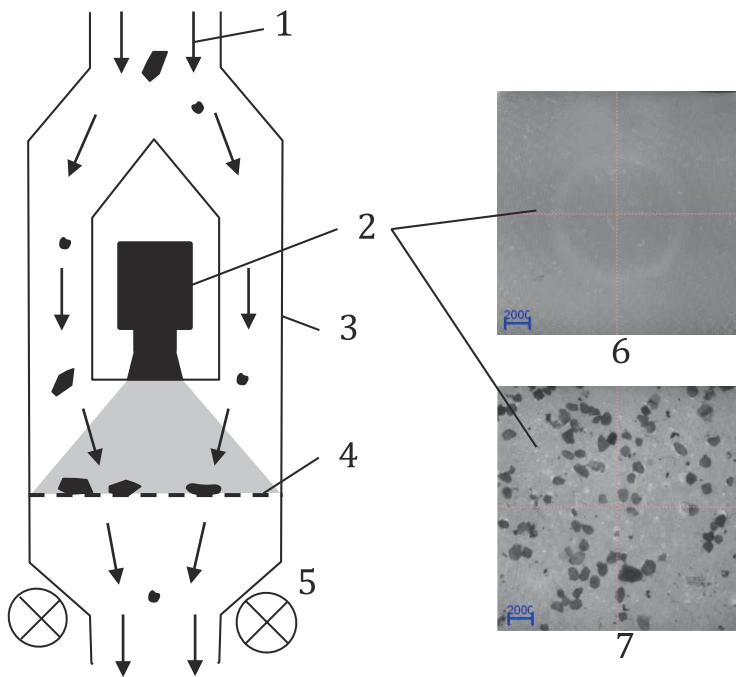


The pore size of the analysis filter is selected to enable only relevant particle sizes to be retained and smaller particles to pass through the filter. The measuring cell, which is located for example at the outlet of an extraction setup where the filter is normally clamped, is fitted with a (transmitted light) illumination source. This provides a high degree of contrast between the particles deposited on the filter and the filter background and assures their detection by the camera.

Further image processing and analysis steps are carried out conform to the light-optical analysis method (binarization and particle measurement). As opposed to automated microscope systems, instead of several image fields being combined to form an overall image, in this case only one image field is analysed. As a result, this system does not offer the optical resolution of microscope systems but is quite suitable for detecting largish single particles.

In each analysis, two images are evaluated — one before the extraction step and one after deposition of the contaminant particles on the filter. The difference between the two corresponds with the particle load extracted from the component.

If particle occupancy on the analysis filter is too high and analysis errors occur due to particles touching or overlapping one another, the analysis filter is backwashed to remove (the majority of) the particle load. Backwashing is performed by reversing the flow of liquid with the aid of suitable pumps and valves or by putting the analysis filter in the other way round.



**Key**

- |   |   |   |                          |
|---|---|---|--------------------------|
| 1 | direction of flow of liquid from extraction apparatus | 5 | illumination             |
| 2 | camera  | 6 | start of the measurement |
| 3 | measuring cell  | 7 | end of the measurement   |
| 4 | analysis filter                                       |   |                          |

**Figure 23 — Cell for the optical analysis of the filter blockade**

**9.4.3.2 Material and equipment**

- a) Measuring cell with:
- camera,
  - analysis filter,

- (transmitted light) illumination,
  - system for backwashing the analysis filter, and
  - image processing and analysis.
- b) Adapter to extraction setup and return feed of test liquid.

#### 9.4.3.3 Procedure

The following procedure shall be adapted to the features of the respective extraction device and analysis system.

- a) Record and analyse an image of the analysis filter to assess its initial state.
- b) Perform the extraction procedure, including the final rinsing step. The complete extraction liquid and final rinsing liquid is then guided through the measuring cell and analysis filter.
- c) Record and analyse an image of the analysis filter after the extraction step.
- d) The difference between the two analyses equates to the particle load extracted from the test component.
- e) Carry out the next extraction or backwash the analysis filter if particle occupancy is too high.

#### 9.4.3.4 Documentation

Particles are analysed and documented in accordance with the procedure for light-optical analysis and grouped into the particle size classes stated in [Clause 10](#).

## 10 Documentation

### 10.1 Overview

This clause specifies the content of the inspection documents, not the format.

Different documents are generated in the course of a cleanliness inspection (see [Figure 24](#)). Depending on the type of cleanliness inspection performed, either a qualification report or an inspection report is written.

The qualification report documents the test conditions, extraction parameters and the results of the qualification tests (declining tests), with the latter being used to determine the routine extraction procedure and thus the related inspection specification.

The inspection report briefly lists the extraction parameters and test conditions as well as the results of routine inspections. In the inspection report, only information related to the inspection performed is required.

The inspection specification contains details of the extraction and analysis parameters together with a clear and easily understandable description of the inspection procedure. The description can be written in a summarized or full version with photos or illustrations being added if desired. The inspection specification may include proof of the qualification or refer to a separate document, the qualification report (for example see [Annex G](#)). Further references (e.g. supplementary agreements) are optional.

The cleanliness inspection document(s) shall contain all the information mentioned in [10.2](#) to [10.8](#) that is necessary to reproduce the cleanliness inspection and assess the results. Further information shall be added as required.

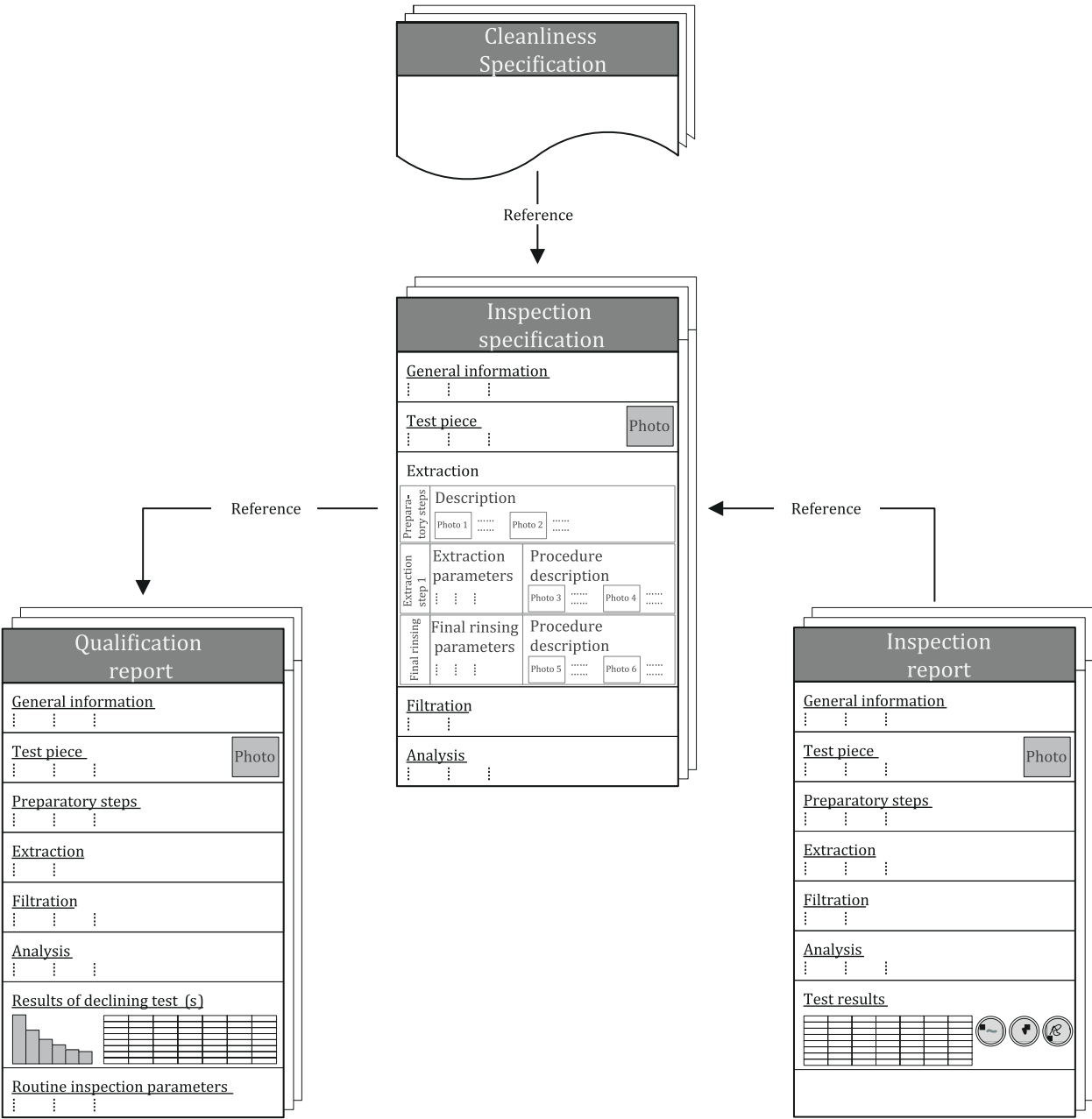


Figure 24 — Cleanliness inspection documents (overview and interrelations)

10.2 General information

“General information” (see [Figure 25](#)) covers higher level information to aid the classification and administration of the documents supplied.

| General information |  |
|---------------------|--|
| Order No.: .....    | Report No.: .....  |
| Customer: .....     | Date of analysis: .....  |
|                     | Contact partner: .....   |
| Test ordered:       | <input type="checkbox"/> Routine inspection <input type="checkbox"/> Double inspection <input type="checkbox"/> Qualification test   |
| Reason for test:    | <input type="checkbox"/> Initial assessment <input type="checkbox"/> Process control <input type="checkbox"/> Modifications, constructional <input type="checkbox"/> ..... |

Figure 25 — General Information

### 10.3 Information about the test component

The test component is described in more detail and identified clearly (see [Figure 26](#)). Additional information which may be useful could include:

- the material the test component is made from, and
- the presence of filmy residues on the test component.

| Test component      |                                 |                      |                     |
|---------------------|---------------------------------|----------------------|---------------------|
| Description: .....  | Condition on delivery: .....    | Photo<br>on delivery | Photo<br>test piece |
| Parts Number: ..... | Test lot size: .....            |                      |                     |
| Batch Number: ..... | Controlled surface: .....       |                      |                     |
| Date removed: ..... | $A_C = \dots \text{cm}^2$       |                      |                     |
| Time removed: ..... | $V_C = \dots \text{cm}^3$       |                      |                     |
| Removed from: ..... | Inspection specification: ..... |                      |                     |

Figure 26 — Information about the test component

### 10.4 Information about preparatory steps

Information about preparatory steps indicates if and when supplementary work steps are required (see [Figure 27](#)). If no information about preparatory steps is mentioned, inspection results could be wrongly evaluated or misinterpreted.

| Preparatory steps                        |  |
|--|--|
| <input type="checkbox"/> None            | <input type="checkbox"/> Isolate controlled surfaces (e.g. sealing, masking)               |
| <input type="checkbox"/> Disassembly     | <input type="checkbox"/> Preclean contaminated surfaces not relevant to controlled surface |
| <input type="checkbox"/> Demagnetization | <input type="checkbox"/> .....   |

Figure 27 — Information about preparatory steps

### 10.5 Information about the extraction

#### 10.5.1 General

The way the extraction step is performed may vary significantly according to the expertise of inspection staff involved. The degree of freedom regarding the extraction step is reduced by documenting the inspection procedure as clearly as possible (see [Figure 28](#)). This aims to make the extraction step reproducible and improve the comparability of inspection results. The number of possible answers should be restricted by the use of checkboxes or dropdown lists. Because the angle or feed rate of an open jet may fluctuate markedly during the extraction step, this information is optional.

| Extraction  |                |   |  |
|---|----------------|---|--|
| Scope of extraction: <input type="checkbox"/> Test piece exclusive packaging<br><input type="checkbox"/> Test piece inclusive packaging   |                | Test environment: <input type="checkbox"/> Undefined<br><input type="checkbox"/> Controlled surface (to be specified):<br><input type="checkbox"/> Cleanroom Class (ISO 14644 -1) .....   |  |
| Extraction method: <input type="checkbox"/> Pressure rinsing<br><input type="checkbox"/> Ultrasonics  |                | <input type="checkbox"/> Internal rinsing<br><input type="checkbox"/> Agitation   | <input type="checkbox"/> Air jet<br><input type="checkbox"/> Air throughflow |
| Solvent: Liquid .....   | Duration ..... | Temperature .....   |  |
| <div>Pressure rinsing</div> <div>.....</div> <div>.....</div>   |                | <div>Internal rinsing</div> <div>.....</div> <div>.....</div>   |  |
| <div>Ultrasonics</div> <div>.....</div> <div>.....</div>  |                | <div>Agitation</div> <div>.....</div> <div>.....</div>  |  |
| <div>Air jet</div> <div>.....</div> <div>.....</div>  |                | <div>Air throughflow</div> <div>.....</div> <div>.....</div>  |  |
| <div>Final rinse, controlled surface 1</div> <div>Manufacturer, extraction device: .....</div> <div>Model, extraction device: .....</div> <div>Manufacturer, nozzle: .....</div> <div>Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet<br/><input type="checkbox"/> Flat jet <input type="checkbox"/> .....</div> <div>Dimensions, nozzle: .....</div> <div>Test liquid: <input type="checkbox"/> Solvent .....<br/><input type="checkbox"/> Neutral cleaner .....<br/><input type="checkbox"/> Other .....</div> <div>Volume flow: ..... l/min</div> <div>Volume of liquid: ..... l</div> <div>Duration: ..... min</div> <div>Angle (test piece : jet): ..... °</div> <div>Distance (test piece : nozzle): ..... mm</div> <div>Nozzle motion speed: ..... mm/s</div> |                | <div>Final rinse, controlled surface 2</div> <div>Manufacturer, extraction device: .....</div> <div>Model, extraction device: .....</div> <div>Manufacturer, nozzle: .....</div> <div>Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet<br/><input type="checkbox"/> Flat jet <input type="checkbox"/> .....</div> <div>Dimensions, nozzle: .....</div> <div>Test liquid: <input type="checkbox"/> Solvent .....<br/><input type="checkbox"/> Neutral cleaner .....<br/><input type="checkbox"/> Other .....</div> <div>Volume flow: ..... l/min</div> <div>Volume of liquid: ..... l</div> <div>Duration: ..... min</div> <div>Angle (test piece : jet): ..... °</div> <div>Distance (test piece : nozzle): ..... mm</div> <div>Nozzle motion speed: ..... mm/s</div> |  |

Figure 28 — Information about the extraction

### 10.5.2 Pressure-rinsing

Pressure-rinsing has the highest number of influencing parameters. Among other things, the cleaning effect of pressure-rinsing is influenced by the nozzle selected. Depending on the nozzle type, the following information should be noted in the section *Dimensions, nozzle*:

- *nozzle cross-section in mm* for a round jet (full jet) nozzle;
- *pressure-rinsing angle in °* and *equivalent nozzle cross-section in mm* for a flat jet (fan-jet) nozzle;
- *nozzle cross-section in mm* and *number of bores* for a parallel jet nozzle.

Additional information can be documented as shown in [Figure 29](#).

| Pressure-rinsing   |  |
|--|--|
| Controlled surface 1   | Controlled surface 2   |
| Manufacturer, extraction device: .....   | Manufacturer, extraction device: .....   |
| Model, extraction device: .....  | Model, extraction device: .....  |
| Manufacturer, nozzle: .....  | Manufacturer, nozzle: .....  |
| Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet | Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet |
| <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       | <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       |
| Dimensions, nozzle: .....  | Dimensions, nozzle: .....  |
| Test liquid: <input type="checkbox"/> Solvent .....                                    | Test liquid: <input type="checkbox"/> Solvent .....                                    |
| <input type="checkbox"/> Neutral cleaner .....   | <input type="checkbox"/> Neutral cleaner .....   |
| <input type="checkbox"/> Other .....   | <input type="checkbox"/> Other .....   |
| Volume flow: ..... l/min   | Volume flow: ..... l/min   |
| Volume of liquid: ..... l  | Volume of liquid: ..... l  |
| Duration: ..... min  | Duration: ..... min  |
| Angle (test piece : jet): ..... °  | Angle (test piece : jet): ..... °  |
| Distance (test piece : nozzle): ..... mm   | Distance (test piece : nozzle): ..... mm   |
| Nozzle motion speed: ..... mm/s  | Nozzle motion speed: ..... mm/s  |

Figure 29 — Information about pressure-rinsing

### 10.5.3 Ultrasonic vibration

With ultrasonic vibration, more influencing parameters are known than are documented. As it is not easy to determine fluctuating sound pressures, pressure peaks and other variables, only details of the extraction parameters shown are documented (see [Figure 30](#)). It is not sufficient to note the ultrasonic output because this depends on the filling level of the ultrasonic device. Instead, information about the power density (output per filling volume) should be given.

| Ultrasonic  |   |
|---|---|
| Controlled surface 1                                | Controlled surface 2                                |
| Manufacturer, extraction device: .....              | Manufacturer, extraction device: .....              |
| Model, extraction device: .....                     | Model, extraction device: .....                     |
| Test liquid: <input type="checkbox"/> Solvent ..... | Test liquid: <input type="checkbox"/> Solvent ..... |
| <input type="checkbox"/> Neutral cleaner .....      | <input type="checkbox"/> Neutral cleaner .....      |
| <input type="checkbox"/> Other .....                | <input type="checkbox"/> Other .....                |
| Filling level, US bath: ..... l                     | Filling level, US bath: ..... l                     |
| Filling level, beaker: ..... l                      | Filling level, beaker: ..... l                      |
| Frequency: ..... Hz                                 | Frequency: ..... Hz                                 |
| Power density: ..... W/l                            | Power density: ..... W/l                            |
| Duration: ..... min                                 | Duration: ..... min                                 |

Figure 30 — Information about ultrasonic vibration

### 10.5.4 Internal rinsing

Internal rinsing may take different forms (see [Figure 31](#)). They range from simple internal rinsing, with the (pressure-rinsing) nozzle being applied hermetically to an opening, right up to complex internal rinsing systems, where parameters such as direction of flow, pulsation, etc. are all adjustable.

If the test liquid flows through the controlled surface in one direction with a periodically-changing flow rate, this is known as pulsation. The pulsation frequency is dependent on time and shall be stated.

| Internal rinsing   |  |
|--|--|
| Controlled surface 1   | Controlled surface 2   |
| Manufacturer, extraction device: .....   | Manufacturer, extraction device: .....   |
| Model, extraction device: .....  | Model, extraction device: .....  |
| Manufacturer, nozzle: .....  | Manufacturer, nozzle: .....  |
| Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet | Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet |
| <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       | <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       |
| Dimensions, nozzle: .....  | Dimensions, nozzle: .....  |
| Dimensions, adapter: .....   | Dimensions, adapter: .....   |
| Test liquid: <input type="checkbox"/> Solvent .....                                    | Test liquid: <input type="checkbox"/> Solvent .....                                    |
| <input type="checkbox"/> Neutral cleaner .....   | <input type="checkbox"/> Neutral cleaner .....   |
| <input type="checkbox"/> Other .....   | <input type="checkbox"/> Other .....   |
| Volume flow: ..... l/min   | Volume flow: ..... l/min   |
| Volume of liquid: ..... l  | Volume of liquid: ..... l  |
| Duration: ..... min  | Duration: ..... min  |
| Pulsation frequency: ..... s <sup>-1</sup>   | Pulsation frequency: ..... s <sup>-1</sup>   |
| Volume flow, max: ..... l/min  | Volume flow, max: ..... l/min  |
| Volume flow, min: ..... l/min  | Volume flow, min: ..... l/min  |
| Reverse flow rinse: .....  | Reverse flow rinse: .....  |

Figure 31 — Information about internal rinsing

10.5.5 Agitation

Agitation is essentially a manual extraction method. The frequency and amplitude of the arm movements can neither be fixed nor measured but shall be approximated as best as possible in the documentation (see [Figure 32](#)).

The term frequency describes the up-and-down and side-to-side movement of the test component. The amplitude describes the distance of travel of the component during this movement, and the number of fillings indicates how often the test component was (re-)filled with clean liquid during the extraction step.

| Agitation   |   |
|---|---|
| Controlled surface 1                                | Controlled surface 2                                |
| Manufacturer, extraction device: .....              | Manufacturer, extraction device: .....              |
| Model, extraction device: .....                     | Model, extraction device: .....                     |
| Test liquid: <input type="checkbox"/> Solvent ..... | Test liquid: <input type="checkbox"/> Solvent ..... |
| <input type="checkbox"/> Neutral cleaner .....      | <input type="checkbox"/> Neutral cleaner .....      |
| <input type="checkbox"/> Other .....                | <input type="checkbox"/> Other .....                |
| Filling volume: ..... l                             | Filling volume: ..... l                             |
| Frequency: ..... Hz                                 | Frequency: ..... Hz                                 |
| Amplitude: ..... mm                                 | Amplitude: ..... mm                                 |
| Duration: ..... min                                 | Duration: ..... min                                 |
| No. of fillings: .....                              | No. of fillings: .....                              |

Figure 32 — Information about agitation

10.5.6 Air jet extraction

Air jet extraction is the same as pressure-rinsing except for the fact that air is used instead of a test liquid (see [Figure 33](#)).

| Air jet extraction   |  |
|--|--|
| Controlled surface 1   | Controlled surface 2   |
| Manufacturer, extraction device: .....   | Manufacturer, extraction device: .....   |
| Model, extraction device: .....  | Model, extraction device: .....  |
| Manufacturer, nozzle: .....  | Manufacturer, nozzle: .....  |
| Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet | Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet |
| <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       | <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       |
| Dimensions, nozzle: .....  | Dimensions, nozzle: .....  |
| Pressure: ..... bar  | Pressure: ..... bar  |
| Duration: ..... min  | Duration: ..... min  |
| Angle (test piece : jet): ..... °  | Angle (test piece : jet): ..... °  |
| Distance (test piece : nozzle): ..... mm   | Distance (test piece : nozzle): ..... mm   |
| Nozzle motion speed: ..... mm/s  | Nozzle motion speed: ..... mm/s  |

Figure 33 — Information about air jet extraction

### 10.5.7 Air through-flow extraction

Air through-flow extraction is the same as rinsing except for the fact that air is used instead of a test liquid (see [Figure 34](#)).

| Air throughflow extraction   |  |
|--|--|
| Controlled surface 1   | Controlled surface 2   |
| Manufacturer, extraction device: .....   | Manufacturer, extraction device: .....   |
| Model, extraction device: .....  | Model, extraction device: .....  |
| Manufacturer, nozzle: .....  | Manufacturer, nozzle: .....  |
| Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet | Type, nozzle: <input type="checkbox"/> Round jet <input type="checkbox"/> Parallel jet |
| <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       | <input type="checkbox"/> Flat jet <input type="checkbox"/> .....                       |
| Dimensions, nozzle: .....  | Dimensions, nozzle: .....  |
| Dimensions, adapter: .....   | Dimensions, adapter: .....   |
| Pressure: ..... bar  | Pressure: ..... bar  |
| Duration: ..... min  | Duration: ..... min  |
| Pulsation frequency: ..... s <sup>-1</sup>   | Pulsation frequency: ..... s <sup>-1</sup>   |
| Volume flow, max: ..... l/min  | Volume flow, max: ..... l/min  |
| Volume flow, min: ..... l/min  | Volume flow, min: ..... l/min  |
| Reverse flow rinse: .....  | Reverse flow rinse: .....  |

Figure 34 — Information about air through-flow extraction

### 10.6 Information about filtration

As well as documenting the actual filtration details, information about drying and any post-treatment steps should also be noted (see [Figure 35](#)).



| Filtration   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
|--|------------------------------|--|-------------|------------------------|--------------------|---------------------|--|----------|---------------------|-------------|------------------------|--------------------|---------------------|--|----------|---------------------|-------------|------------------------|--------------------|---------------------|
| <table><tr><td>Filter 1</td></tr><tr><td>Manufacturer: .....</td></tr><tr><td>Type: .....</td></tr><tr><td>Filter material: .....</td></tr><tr><td>Diameter: ..... mm</td></tr><tr><td>Pore size: ..... µm</td></tr></table> | Filter 1                     | Manufacturer: .....                            | Type: ..... | Filter material: ..... | Diameter: ..... mm | Pore size: ..... µm | <table><tr><td>Filter 2</td></tr><tr><td>Manufacturer: .....</td></tr><tr><td>Type: .....</td></tr><tr><td>Filter material: .....</td></tr><tr><td>Diameter: ..... mm</td></tr><tr><td>Pore size: ..... µm</td></tr></table> | Filter 2 | Manufacturer: ..... | Type: ..... | Filter material: ..... | Diameter: ..... mm | Pore size: ..... µm | <table><tr><td>Filter 3</td></tr><tr><td>Manufacturer: .....</td></tr><tr><td>Type: .....</td></tr><tr><td>Filter material: .....</td></tr><tr><td>Diameter: ..... mm</td></tr><tr><td>Pore size: ..... µm</td></tr></table> | Filter 3 | Manufacturer: ..... | Type: ..... | Filter material: ..... | Diameter: ..... mm | Pore size: ..... µm |
| Filter 1   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Manufacturer: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Type: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Filter material: .....   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Diameter: ..... mm   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Pore size: ..... µm  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Filter 2   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Manufacturer: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Type: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Filter material: .....   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Diameter: ..... mm   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Pore size: ..... µm  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Filter 3   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Manufacturer: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Type: .....  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Filter material: .....   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Diameter: ..... mm   |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Pore size: ..... µm  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Drying   |                              | Pre-conditioning                               |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Devices: <input type="checkbox"/> None (environment)   | <input type="checkbox"/> Yes | <input type="checkbox"/> No                    |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| <input type="checkbox"/> Drying cabinet  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| <input type="checkbox"/> Desiccator  |                              |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Temperature: .....°C   | Post-treatment               |  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
| Duration: ..... min  | Liquid                       | <input type="checkbox"/> Solvent .....         |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
|  |                              | <input type="checkbox"/> Neutral cleaner ..... |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
|  |                              | <input type="checkbox"/> Other .....           |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |
|  | Volume of liquid: .....      | l  |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |  |          |                     |             |                        |                    |                     |

Figure 35 — Information about analysis filtration

10.7 Information about the analysis

10.7.1 General

Details and settings of the analysis system are documented. If the extraction step and analysis are performed in different places or different room qualities, the test environment shall be documented in the same way as shown in 10.5.

10.7.2 Standard analysis

10.7.2.1 Gravimetric analysis

Among other things, the weighing result of a gravimetric analysis is dependent on the room temperature. If this is not documented anywhere else, the room temperature should be noted in the gravimetric analysis (see Figure 36).

| Gravimetry          |   |
|---------------------|---|
| Manufacturer: ..... | Date of last calibration:.....  |
| Model: .....        | Resolution of balance: <input type="checkbox"/> ± 0,1 mg <input type="checkbox"/> ± 0,01 mg <input type="checkbox"/> ± 0,001 mg |

Figure 36 — Information about balance for gravimetric analysis

10.7.2.2 Light-optical analysis

Light-optical devices can be calibrated using particle standards. The date of the last calibration shall be documented. The scale shall be stated as the magnification per pixel in [µm/pixel] (see Figure 37).

| Light optical analysis   |                           |
|--------------------------|---------------------------|
| Manufacturer: .....      | Particle standard: .....  |
| Model: .....             | Date of last check: ..... |
| Pixel resolution: .....  | µm/Pixel                  |
| Analysis diameter: ..... | mm                        |
| Brightness: .....        | %                         |
| Threshold value: .....   |                           |

Figure 37 — Information about light optical analysis

### 10.7.3 Extended analysis (informative)

Information about extended analyses may vary depending on the analysis system utilized. An example of information about a scanning electron microscope with EDX detector is shown in [Figure 38](#).

| Scanning Electron Microscopy / Energy Dispersive X-ray spectroscopy (SEM / EDX) |                           |
|---|---------------------------|
| Manufacturer: .....   | Particle standard: .....  |
| Model: .....  | Date of last check: ..... |
| Acceleration voltage: .....   | keV                       |
| Analysis diameter: .....  | mm                        |
| Working distance: .....   | mm                        |
| Process: <input type="checkbox"/> Automated <input type="checkbox"/> Manual     |                           |

**Figure 38 — Information about SEM/EDX for extended analysis**

### 10.7.4 Shortened analysis (informative)

The information shown in [Figure 39](#) regarding a shortened analysis refers to an automatic particle counter.

| Optical particle counter (OPC) |                                 |
|--------------------------------|---------------------------------|
| Manufacturer: .....            | Coincidence limit: .....        |
| Model: .....                   | Date of last calibration: ..... |
|                                | Calibration material: .....     |
| Extraction liquid: .....       | ml                              |
| Dilution factor: .....         |                                 |
| Measuring interval: .....      | min <sup>-1</sup>               |
| Nominal volume flow: .....     | ml/min                          |
| Detection volume: .....        | ml                              |

**Figure 39 — Information about optical particle counter for shortened analysis**

## 10.8 Reporting of the inspection results

### 10.8.1 General

Information about cleanliness values shall be related to one of the following units of reference:

- number of components tested  $n = [1]$ ;
- wetted surface area of test component  $A_C = [\text{cm}^2]$ ;
- wetted volume of test component  $V_C = [\text{cm}^3]$ .

### 10.8.2 Gravimetric analysis

The result of a gravimetric analysis is the residue mass  $m = m_2 - m_1$ , with the last digit being mathematically rounded. The masses  $m_2$  and  $m_1$  are read off using the resolving capacity of the weighing balance. The resulting particle mass  $m$ , which is calculated from the difference between the residue mass and the unit of reference, shall be documented.

#### Mass related to number of components tested

$$m_C = \frac{m}{n} = \left[ \frac{\text{mg}}{1} \right]$$

The unit used is mg per ( $n$ ) component(s).

**Mass related to controlled surface**

$$m_A = \frac{m \times 1\,000}{A_C} = \left[ \frac{\text{mg}}{1\,000 \text{ cm}^2} \right]$$

**Mass related to controlled volume**

$$m_V = \frac{m \times 100}{V_C} = \left[ \frac{\text{mg}}{100 \text{ cm}^3} \right]$$

**10.8.3 Light-optical analysis**

Light-optical systems determine the length and/or width of individual particles. The particles are also classified into a specified length or width interval (or size class).

Length/width intervals other than the size classes listed in [Table 8](#) should only be documented if absolutely necessary, e.g.  $100 \mu\text{m} \leq x < 200 \mu\text{m}$ ,  $200 \mu\text{m} \leq x < 300 \mu\text{m}$ , etc. (added effort).

The size classes now include letters L, M and N (see [Table 8](#))

**Table 8 — (Particle) size classes**

| Size class | Size $x$ [ $\mu\text{m}$ ] |
|------------|----------------------------|
| B          | $5 \leq x < 15$            |
| C          | $15 \leq x < 25$           |
| D          | $25 \leq x < 50$           |
| E          | $50 \leq x < 100$          |
| F          | $100 \leq x < 150$         |
| G          | $150 \leq x < 200$         |
| H          | $200 \leq x < 400$         |
| I          | $400 \leq x < 600$         |
| J          | $600 \leq x < 1\,000$      |
| K          | $1\,000 \leq x < 1\,500$   |
| L          | $1\,500 \leq x < 2\,000$   |
| M          | $2\,000 \leq x < 3\,000$   |
| N          | $3\,000 \leq x$            |

The particle size distribution shall include information about the unit of reference. The normed particle count  $H$  is obtained from the ratio between the absolute particle count  $h$  and the unit of reference.

**Particle count related to the number of components tested**

$$H_C = \frac{h}{n} = [1]$$

The unit used is particles per ( $n$ ) component(s).

**EXAMPLE** A test lot of 4 components is inspected ( $n = 4$ ) and 13 particles in Size Class G ( $150 \leq x < 200 \mu\text{m}$ ) are detected ( $h = 13$ ). This gives the normed particle count  $H_C = 13/4 = 3,25$ . Rounding to at least one position after the decimal point finally results in  $H_C = 3,3$ .