INDUSTRIAL

CIX100
Basics of Technical Cleanliness

EVIDENT

Cleanliness Inspection

The growing complexity of technical products in the automotive, aerospace, and electrical engineering and medical device manufacturing industries requires clean production conditions and components. Residues on the surface of technical devices can cause poor device performance and shorter component lifespans. The presence of particle residue in the manufacturing and assembly processes can cause production downtime or waste of materials and energy. The installation of a contamination control system is an essential component for establishing a system for clean production.

In a contamination control system, random parts are taken from the production line and examined. The examined parts are washed and the extracted impurities are captured on a membrane filter. The cleanliness inspection system detects and classifies the particles on this filter membrane. The characterization of the impurities is carried out in accordance with international standards—such as ISO 16232 (VDA 19.1) or ISO 4406. Metallic particles can be distinguished from non-metallic particles and fibers are identified. When the analysis is complete, the results are presented in a report.

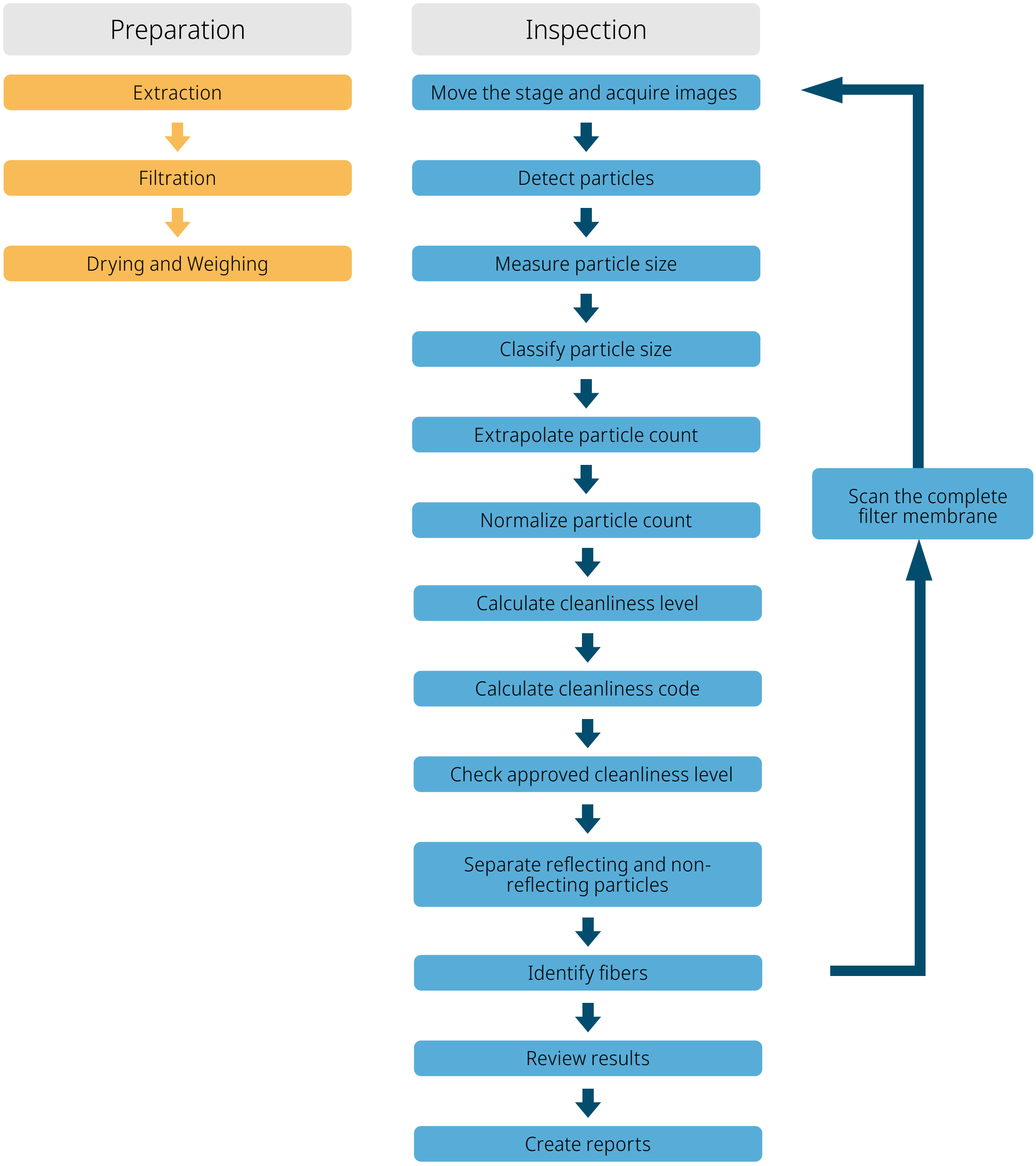
The CIX100 system combines ease of use with user convenience and complies with many standards (VDA 19.1, VDA 19.2, ISO 16232, ISO 4406, ISO 4407, USP 788, and more, or factory or customer standards). The system's robust and maintenance-free design utilizes high-quality optical components to help ensure excellent repeatability and accuracy. Optimized for cleanliness inspection, the CIX100 system has seamlessly integrated hardware and software that makes the system intuitive and easy to use.

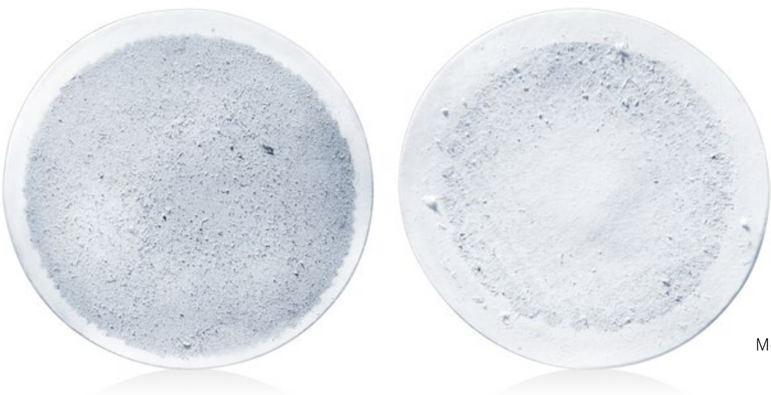
The CIX100 system can be used to inspect dark contaminants on a light background or light contaminants on a dark background for additional flexibility.

Automotive, aerospace, electrical engineering and medical device manufacturing industries requires clean production conditions and components

Workflow of Cleanliness Inspection

The workflow for detecting particles on a filter membrane consists of the following steps:





Membrane filters with extracted impurities

Preparation: Extraction

Contaminant particles are first separated from the components being tested. This is done in an extraction cabinet in a clean room. The contaminants can be removed from the parts via a liquid or in an ultrasonic bath. For the vast number of inspected components used in automobiles, extraction via a liquid is suitable. The liquid used in the extraction process must be compatible with the component as well as with the filtration device. Well-known manufacturers of extraction cabinets are:

- Gläser GmbH (www.glaeser-gmbh.de)
- HYDAC INTERNATIONAL GmbH (www.hydac.com)
- Brändle GmbH (www.braendle-gmbh.eu)

The extraction cabinet must be cleaned regularly in order to keep it free of contamination. To do this, the empty cabinet is flushed several times, and the washing rinse is filtered and examined for particles. Be sure to follow the cleaning protocol of the extraction cabinet manufacturer.
After 3 or 4 washing cycles, you will have a baseline for the amount of residue typically found in the cabinet. This forms a background value for your given cleanliness inspection system (rinse, cabinet, and filter). It is sufficient to weigh the filter membranes to establish this baseline value.

Extraction is the first step of the preparation process

Preparation: Filtration

The washing rinse is filtered through a membrane and the extracted particles are collected. This filter is clamped in a holder that is part of the extraction cabinet. If oil is being examined, it is filtered directly. A defined quantity (about 50 ml) of the oil is drawn through a vacuum filter holder, and the particles are captured on the filter.

Well-known manufacturers of vacuum filter holders are:
- Sartorius (www.sartorius.de)
- Merck Millipore (www.merckmillipore.com)

Typically, the filter is not completely covered with residue particles because the border of the filter is covered by a seal, resulting in a smaller flow-through area.

Various filter sizes, ranging from 25 mm to 90 mm in diameter, are available. Filters with a diameter of 47 mm are common and are the quasi-standard for technical cleanliness inspection. Filters are commonly available in four different membrane types:
- Cellulose: Excellent compatibility with aqueous solutions.
- Polyester: Uniform image background — easy to set thresholds for particle detection.
- Glass fiber: Ideal for solutions with a high content of suspended solids or high viscosity.
- Nylon mesh: Very good for almost all solvents, but needs a white support layer because the mesh is transparent.

Well-known manufacturers of membrane filters are:
- Merck Millipore (www.merckmillipore.com)
- Sartorius (www.sartorius.de)
- SEFAR (www.sefar.com)

Filtration is the second step of the preparation process

Preparation: Drying and Weighing

The filter membrane must be dried for the further analysis. The rinse fluid or oil can be removed in an exsiccator, a drying oven, or by using dedicated equipment.
Well-known manufacturers of drying devices are:
• DURAN Group GmbH (www.duran-group.com)
• BINDER GmbH (www.binder-world.com)
• Gläser GmbH (www.glaeser-gmbh.de)

The dried filter membrane with the impurities on it is weighed using an analytical balance with integrated wind shield. The gravimetric result serves as a first value for the residue particles, but the size, shape, and other properties of the particles remain unknown.

Well-known manufacturers of analytical balances are:
• Sartorius (www.sartorius.de)
• Mettler-Toledo, LLC (www.mt.com)
• Fisher Scientific Company LLC (www.fishersci.com)

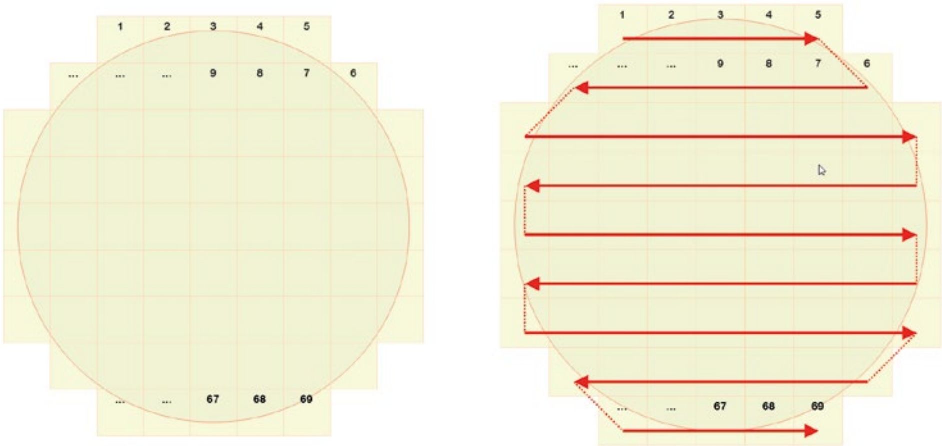
The weighed filter membrane is now mounted on a filter holder and is ready for particle inspection.

Weighing is the third and final step of the preparation process

Inspection: Acquire Images and Move the Stage

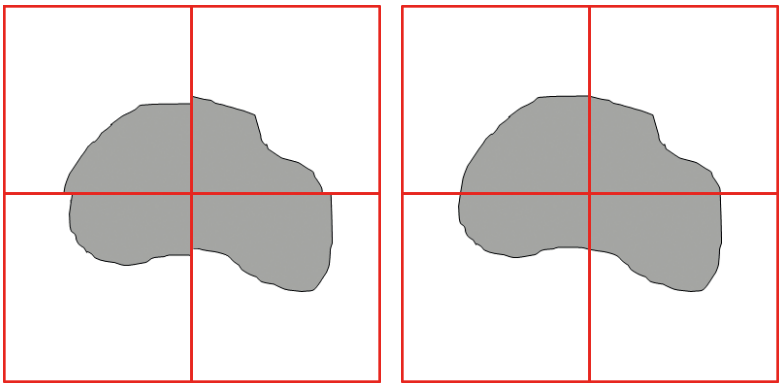
Once the filter is mounted on the microscope's stage, the cleanliness inspector can acquire images fully controlled through software. It is important to have a well-calibrated pixel size because the resulting size of the particles is sensitive to it. The image resolution is in the range of 1 µm when using a 10X objective lens.

It is necessary to detect all particles on the filter membrane, but only once. The filter membrane is split into frames within the field of view of the camera, and the microscope's stage moves to scan the entire membrane.



Scan direction of the microscope stage

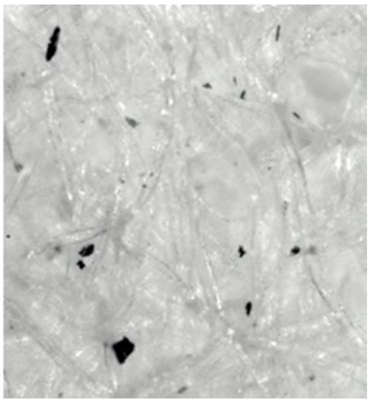
There is no need to have overlapping images. The motorized stage is very precise, enabling the filter membrane to be carefully positioned. When using a 10X objective, it takes about 1700 individual images to cover the entire filter area. This process takes less than 10 minutes — including image acquisition and analysis.
All of the images must be acquired side-by-side. The CIX system accomplishes this by coordinating the movement of the camera (image) and stage during the acquisition process.



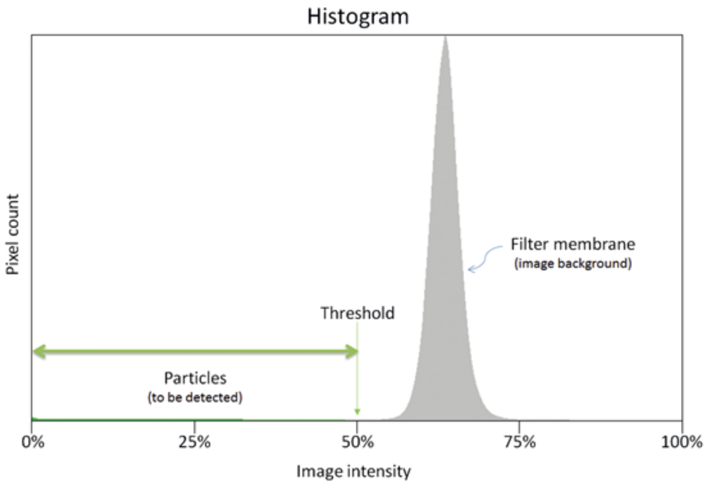
An uncorrected movement (left) and a corrected movement (right)

Inspection: Detect Particles

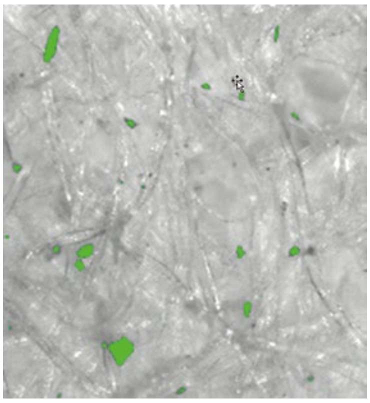
When examining filter membranes, the particle appears dark on the bright background.



The detection or segmentation of the image is used to combine a set of pixels in the image. This combined pixel area is called a particle.



The range of intensity for the particles starts at 0 (black) and is only necessary when determining the particle's upper-intensity threshold:



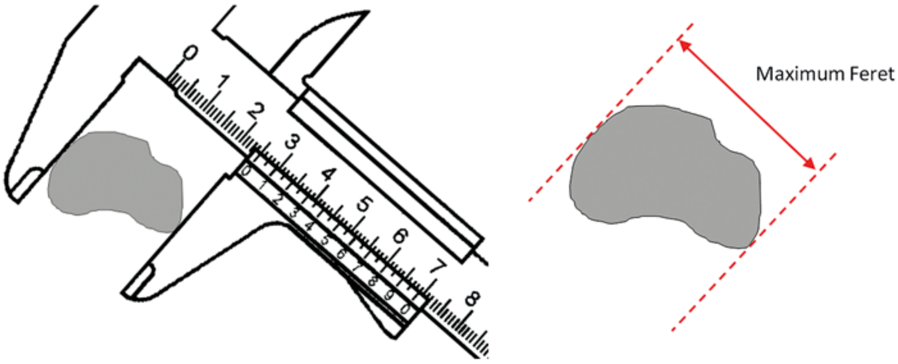
For the investigation of a complete filter membrane, it is important that particles are also detected if they extend beyond the field of view of individual image frames. A particle might be split between two or more images, but the CIX system's software will render an image of the particle that is the correct size and shape.

Inspection: Measure the Particle Size

Each detected particle can be described by different parameters. The most important particle parameters are the maximum Feret diameter and the equivalent circle diameter. These measurements are most commonly used to describe the size of a particle.

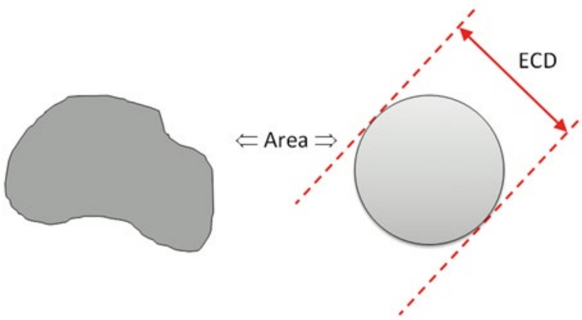
Maximum Feret Diameter

The maximum Feret diameter is the maximum distance of parallel tangents at opposing particle borders. This is similar to measuring an object using a caliper.



Equivalent Circle Diameter

The equivalent circle diameter (ECD) is the diameter of a circle that has an area equal to the area of the particle.



Both parameters measure the length of the particle. Other particle parameters can be used to measure a particle's area, shape, and reflectivity. These traits are used to recognize special particle families, like fibers and reflecting particles. All resulting values can be shown in the result sheets and in the final report.

For some inspection standards, it is also recommended to measure the share of the membrane area covered by all particles in percent. This occupancy should be approximately 1% to 2% and, in most cases, is less than 7%.

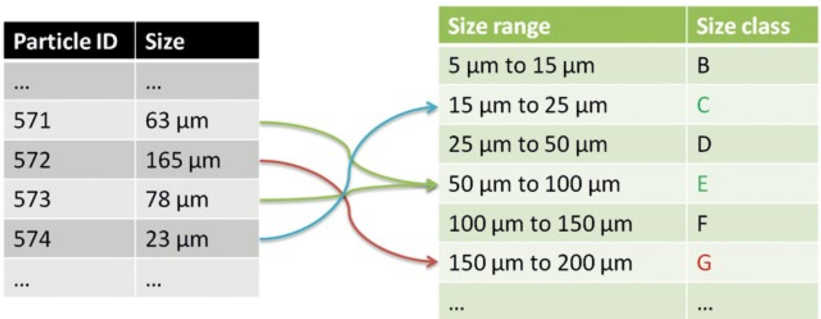
Inspection: Classify Particles

The particle detection step results in a sheet with results for each detected particle. The size (typically the maximum Feret diameter) of each particle is also listed. All particles are grouped into different size classes, making the sheet short and enabling a better comparison of the measurements.
The particle classification can be defined by the user. The classification parameters and the division of the classes are defined in various international standards. There are two major groups of size classes:

Differential classes
The size classes are defined by a minimum and a maximum particle size. Each particle is placed in only one class. A typical standard with differential size classes is the "ISO 16232" where the classes are defined as:
• Class B: All particles where the maximum Feret diameter is larger than 5 µm but smaller than 15 µm
• Class C: All particles where the maximum Feret diameter is larger than 15 µm but smaller than 25 µm
• Class D: All particles where the maximum Feret diameter is larger than 25 µm but smaller than 50 µm
For example, under this standard, a particle with a diameter of 20 µm will be placed into size class C.

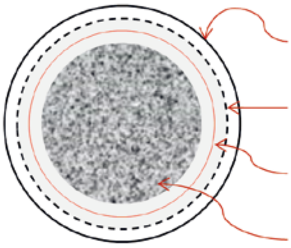
Cumulative classes
The size classes are defined by a minimum particle size. As a result, it is possible that particles will be counted and placed into more than one class. A typical standard with cumulative size classes is the "ISO 4406" where the classes are defined as:
• Class B: All particles where the maximum Feret diameter is larger 5 µm
• Class C: All particles where the maximum Feret diameter is larger 15 µm
For example, using this standard, a particle with a diameter of 20 µm will be counted in size class B and C.
Notice: Here and in the later description of the international standards, the size classes are displayed in green. This is done to have an easier presentation of size classes, contamination level, and resulting cleanliness code.

Example for ISO 16232:



Inspection: Extrapolate Particle Count

A defined area on the filter is scanned and checked for particles. The different areas on the filter are defined as follows:



Filter size

Standard filters have a diameter of 47 mm, resulting in a whole filter area of 1735 mm^2. Other filter sizes - such as 25 mm or 55 mm in diameter - are also available. However, these are used much less frequently.

Flow through area

The filter is not completely covered with particles. Particles are only found in the area where the washing rinse passed through the filter during the filtration process. This flow through area can be set by the operator and must be a circular area in the center of the filter with a diameter of less than 42 mm.

Maximum scan area

The maximum scan area has a diameter of 42 mm and an area of 1385 mm^2.

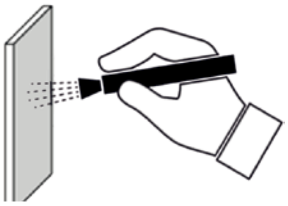
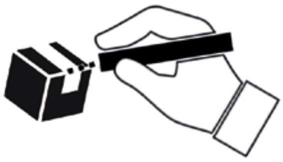
Inspection area

The actual scan area can be defined by the user. Typically, the maximum possible scan area is used for the scan, but the inspection area can be smaller. A smaller inspection area leads to fewer images, speeding up the time it takes to inspect a filter.

All particles are detected when the flow through area is completely inside the inspection area. When the inspection area is smaller than the flow through area, the system needs to extrapolate the number of detected particles. The flow through area has to be set in the software and is used for normalization.

Inspection: Normalize Particle Count

The absolute or extrapolated count of particles must be normalized on a reference value.
Depending on the standard used and the filter being tested, the number of particles is normalized to a comparison value. This enables users to compare multiple measurements — even if the samples have different sizes.
Depending on the method, a different size for normalization may be used. Select the respective normalization standard in the software (e.g. “ISO 16232 (A)” or “ISO 16232 (V)”).

Wetted area 	Normalization on a wetted surface area is used when the contaminant particles were washed from a sample surface.	The resulting particle count is normalized on an area of 1000 cm^2.
Wetted volume 	Normalization on a wetted sample volume is used when the contaminant particles were washed from a larger sample .	The resulting particle count is normalized on an area of 100 cm^3.
Wetted parts 	Normalization on wetted sample parts is used when the contaminant particles were washed from a number of similar samples.	The resulting particle count is normalized on a single sample part.
Filtered fluid 	If the filtered fluid itself is analyzed and the contaminant particles are not washed from a sample, the normalization has to be done on the amount of filtered fluid.	The resulting particle count is normalized on a volume of 1 ml or 100 ml of filtered fluid.

Notice that the unit “cm^3” is used for the washed volume and the unit “ml” is used for the filtered fluid. The different units are selected to avoid mixing the values of washed sample volume and filtered fluid.

Inspection: Calculate Contamination Level

For most cleanliness standards, the actual number of the measured (or extrapolated) particles is not displayed; instead, a calculated number is represented. The contamination level is checked for each particle size class. This is a second level of classification, but this time the particles are not classified according to their size. Instead, the classes are arranged according to the number of particles in the class. These contamination levels enable users to quickly and easily compare different cleanliness measurements, even if it sometimes is an oversimplification.

Typical contamination levels are defined in the standard “ISO 16232” where the levels are:
• Level 00: No particles per 1000 cm^2 surface area
• Level 0: Less than 1 particle per 1000 cm^2 surface area
• Level 1: More than 1 but less than 2 particles per 1000 cm^2 surface area
• Level 2: More than 2 but less than 4 particles per 1000 cm^2 surface area
• Level 12: More than 2000 but less than 4000 particles per 1000 cm^2 surface area
These contamination classes are defined for most of the international standards. Users can define up to 26 different levels that will be measured for each particle size class. These contamination levels are usually similar for each size class (e.g. for ISO 16232) but they can be defined differently for each particle size class (e.g. for SAE AS4059).
Note: Here and in the later description of the international standards, the contamination levels are displayed in red. This is done to have an easier presentation of size classes, contamination level, and resulting cleanliness code .

Example for ISO 16232 (A):

Class	Particles Absolute	Particles per 1000 cm^2
B	1476	2059.0
C	598	834.2
D	179	249.7
E	94	131.1
F	5	7.0
G	2	2.8
...	...	...

Particles	Contamination level
...	...
2 to 4	2
4 to 8	3
8 to 16	4
16 to 32	5
32 to 64	6
64 to 130	7
130 to 250	8
250 to 500	9
500 to 1000	10
1000 to 2000	11
2000 to 4000	12
...	...

Inspection: Define Cleanliness Code

Some standards reduce the representation of the measurement data to only a brief description. This cleanliness code is dependent on the standard and is composed of the size classes and the contamination levels of particles found.

Example for ISO 16232 (A):
Step (1): Detect and measure particles
Step (2): Normalize and classify particles
Step (3): Check contamination level

1

Particle	Size
...	...
571	63 µm
572	165 µm
573	78 µm
574	23 µm
...	...

2

Range	Class	Count
5 µm to 15 µm	B	2059.0
15 µm to 25 µm	C	834.2
25 µm to 50 µm	D	249.7
50 µm to 100 µm	E	131.1
100 µm to 150 µm	F	7.0
150 µm to 200 µm	G	2.8
...	...	...

3

Particles	Contamination level
...	...
2 to 4	2
4 to 8	3
8 to 16	4
16 to 32	5
32 to 64	6
64 to 130	7
130 to 250	8
250 to 500	9
500 to 1000	10
1000 to 2000	11
2000 to 4000	12
...	...

The resulting component cleanliness code “CCC” for this example is

A (B12/C10/DE8/F3/G2/HIJ00)

Comments:
- This form of cleanliness code is for the ISO 16232 standard only. Other standards define a different cleanliness code.
- The first “A” indicates the normalization to the sample to a 1000 cm² surface.
- Neighboring classes with the same contamination level can be combined.

Inspection: Check for Maximum Approval

The actual task of a cleanliness inspection is to measure contamination and describe the results according to the selected standard. Checking and approving a maximum value is an option, but is not always part of a cleanliness inspection.

CIX Approach

The maximum limit is specified in the inspection configuration. This may be the absolute number of particles or a maximum cleanliness code. This value is checked during the examination of the filter membrane, and the user is instantaneously alerted when the maximum allowed value is exceeded. The operator is free to stop the measurement process and investigate the source of the contamination.

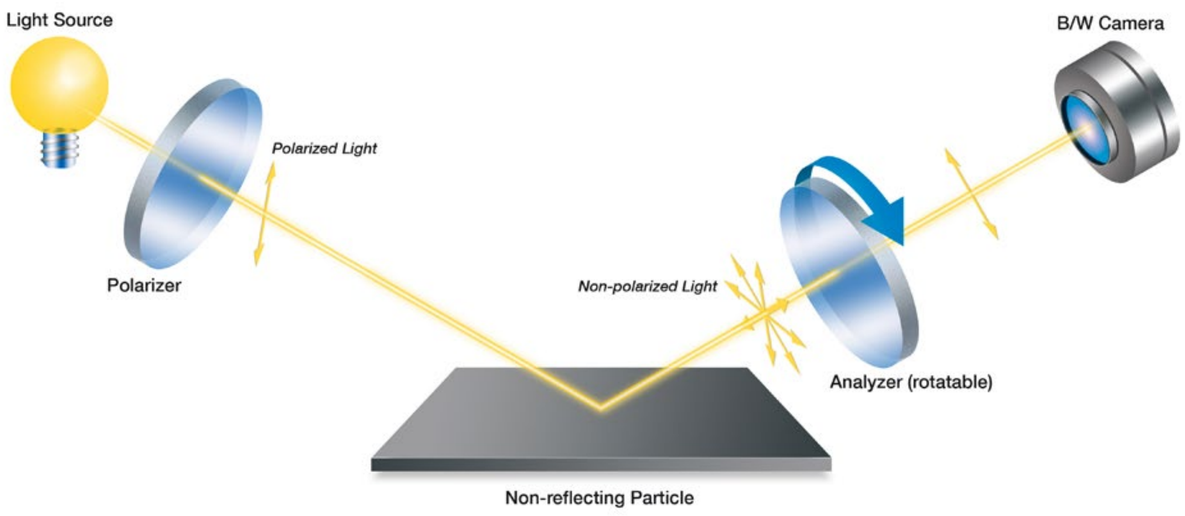
The following example shows the CIX software's screen when testing for the maximum approval when the filter membrane is scanned. The image on the left shows the data readout after 2 minutes of scanning while all the results are still OK. The image on the right shows the scan result 2 minutes later. Now, there are too many particles in size classes B, H, and I. Therefore the overall approval is now "NOK".

Inspection: Separate Reflecting/Non-Reflecting Particles

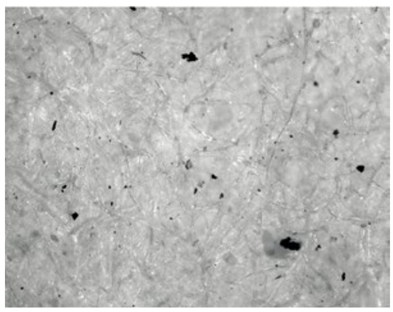
Why should reflecting particles be recognized?
Metallic particles are much harder and potentially more damaging to the components being tested. Distinguishing between metallic and non-metallic particles is based on their different behaviors of the reflected incident light.

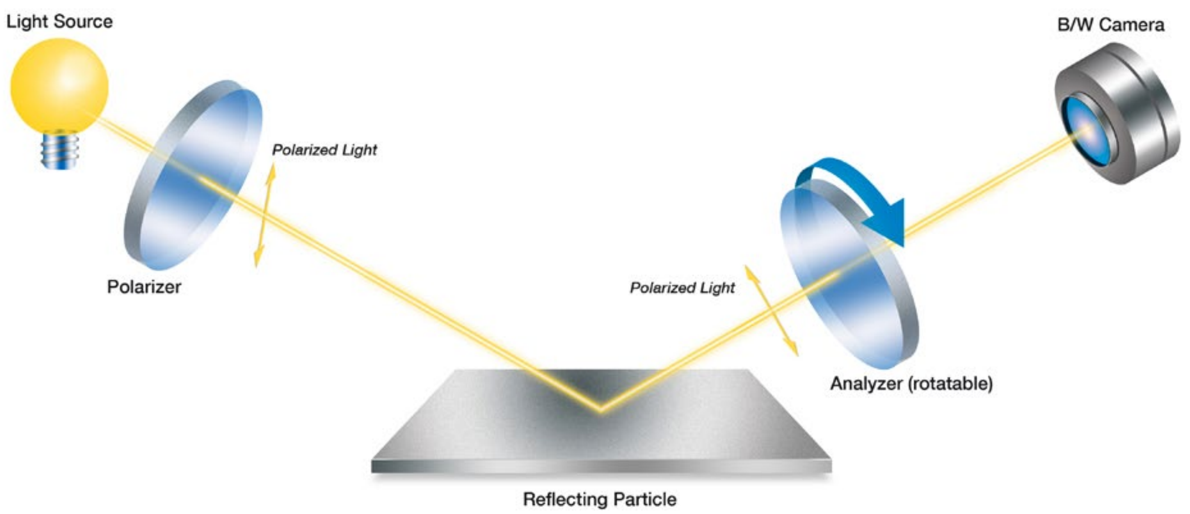
The incident light on the filter membrane and on the non-metallic particles is scattered diffusely. No matter the incident light, the "reflected" light is not polarized. Even if the incident light is polarized, there is no effect when analyzing the polarization. The filter membrane is always brighter than the particles on it.

The Classical Approach

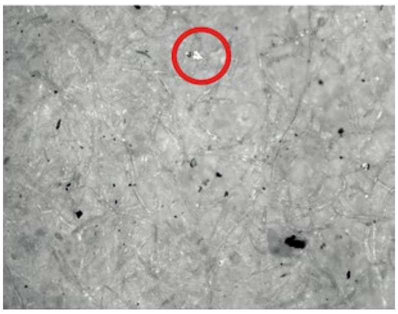


When the incident light hits a metallic particle, it produces a real reflection. The light reflected off a metallic surface does not change the polarization of the light. This difference is exploited in the "classical" method of cleanliness inspection. The polarization of the reflected light can be analyzed by the camera and software. Metallic particles are very bright when the polarizer and analyzer are set to parallel.



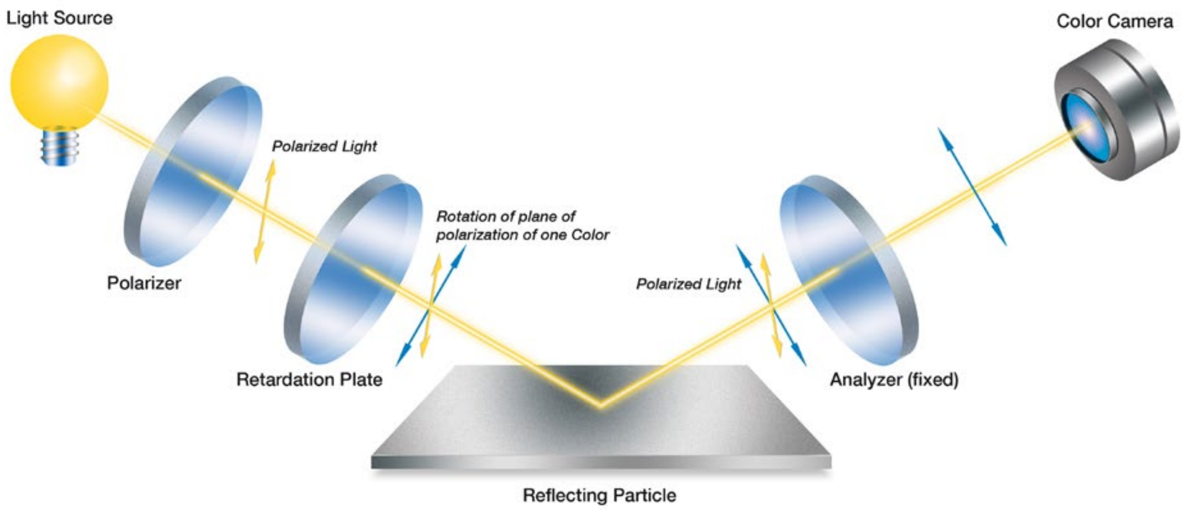


The "classical" detection of metallic particles requires two images. The first image detects all particles and the second image highlights the metallic particles. The analyzer must be rotated 90° between the two sets of image acquisition. This is time-consuming and needs special adjustments and alignment of the two images.

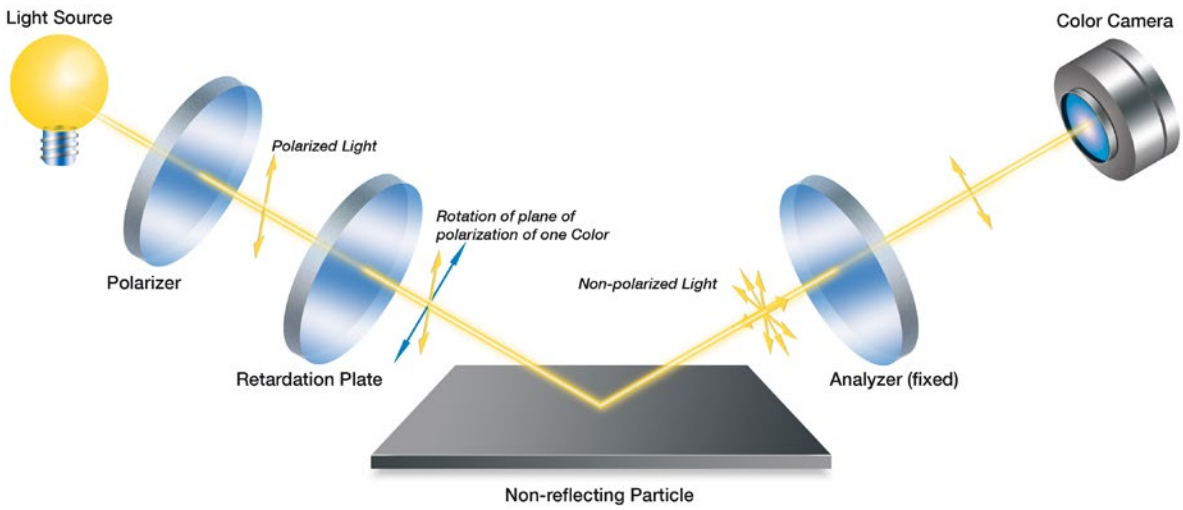


The CIX System's Approach

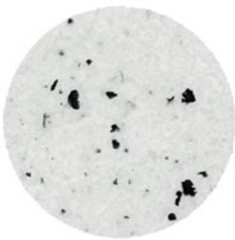
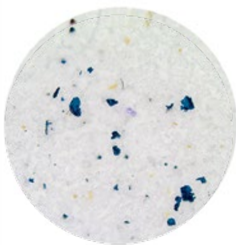
The CIX system has an innovative method that recognizes reflective and non-reflective particles in a single scan. The incident light beam is also polarized. The polarization of one band of the light spectrum is changed using a retardation plate. As a result, the polarization of the incident light is different for different colors.
The diffuse reflection of non-metallic particles or the filter membrane is identical to the classical setup. The reflected light is non-polarized in all color ranges and does not need to be analyzed. The filter membrane is brighter than the dark particles on it.

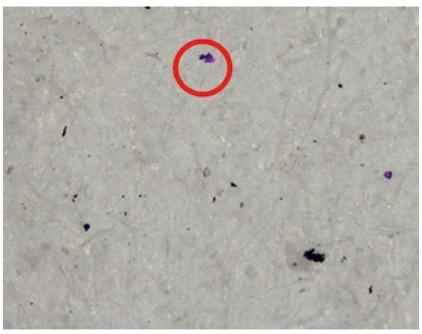


The reflection of metallic particles also follows the classic principle and preserves the polarization of the light. But because the polarization of each color is known, it is possible to detect metallic particles directly in the color image. Metallic particles get bright only for a special color.



Only one color image is required to separate reflecting (metallic) and non-reflecting (non-metallic) particles. A second scan is not required, saving users time. Because no mechanical parts have to be rotated, it saves wear and tear on the instrument.

'Classical' method		Single-scan solution: Combined
First recording: Non-reflecting	Second recording: Reflecting	
		

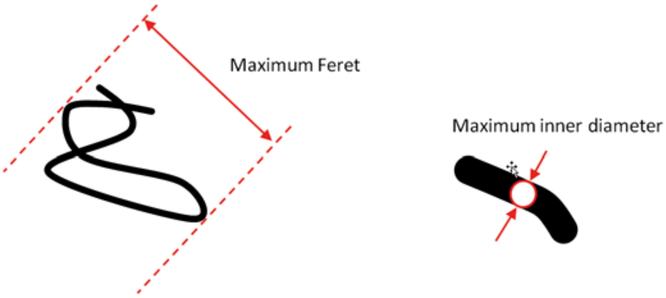


Inspection: Identify Fibers

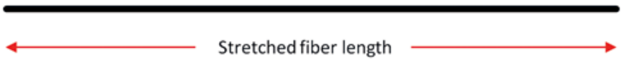
Why should fibers be recognized?

Particles are impurities that are washed from the sample surface. The fibers often have a different origin, such as work clothes or rags, or the source of the fibers can be dust from the laboratory environment. Fabric fibers are usually not so critical to the function of the technical component. Fibers should, therefore, be recognized but their presence is often disregarded when assessing the cleanliness.

A fiber particle is characterized by its elongated shape. The aspect ratio of the length to the width is called fibrousness and must be in the range of 10:1 to 20:1, depending on the standard used. This means that the fibers must be significantly elongated as compared to other fiber measurements, like asbestos investigations where the individual fibers are straight like a needle but the fibrousness need only be 3:1.



The fibers on the filter membrane might not be straight but folded. This is why the measurement of the Feret diameter does not give a good result for the fiber length. As a first estimation, the fiber length can be calculated as the ratio of its area and the maximum inner diameter. This is possible if the fiber is presumed to have the same width over its whole length.



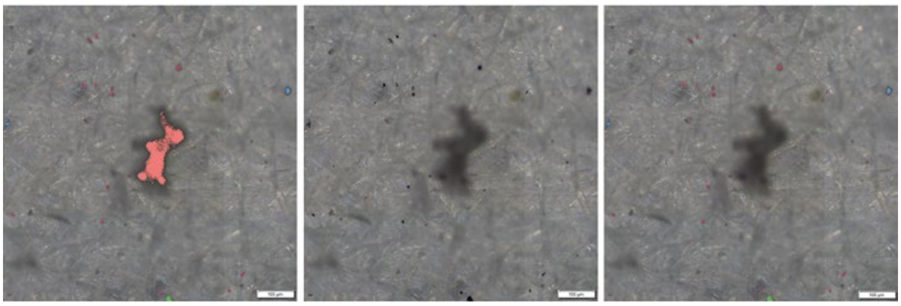
More precise measurements of the fiber length follow the fiber's skeleton and calculate the stretched fiber length. This is time-consuming and cannot be done for all detected fibers.

Inspection: Review Results

The detected and classified particles can be inspected by the operator prior to the creation of the report. This is a chance to double check and confirm the cleanliness results before presenting them. Typically, the largest particles will be rechecked. The following operations are possible during the review of results:

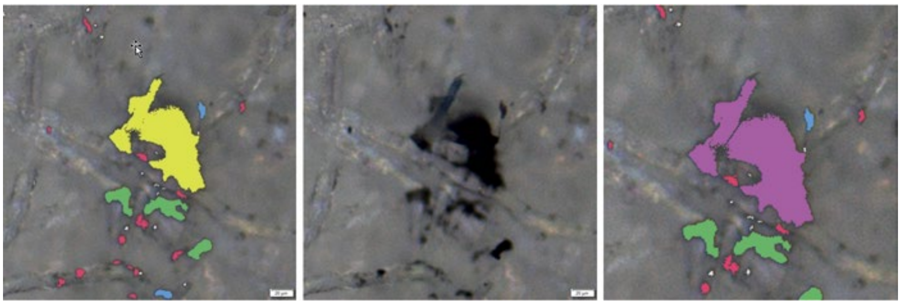
1. Delete Particles

Errors on the membrane, such as artifacts caused by incorrect drying, can be detected as particles and removed in the review process.



2. Split Particles

Particles that are too close to each other may be detected as a single big particle. In this case, the particle can be split into its components.



3. Merge Particles

Fragments of a particle can be combined if they obviously belong together. This is sometimes the case when a fiber is not completely focused and, thus, not completely detected.

4. Change Particle Family

The family type of the particle can be changed. The operator can change the particle from “non-reflective” to “reflective” (metallic).

Note: This is not illustrated by the example images because there is no visible change.

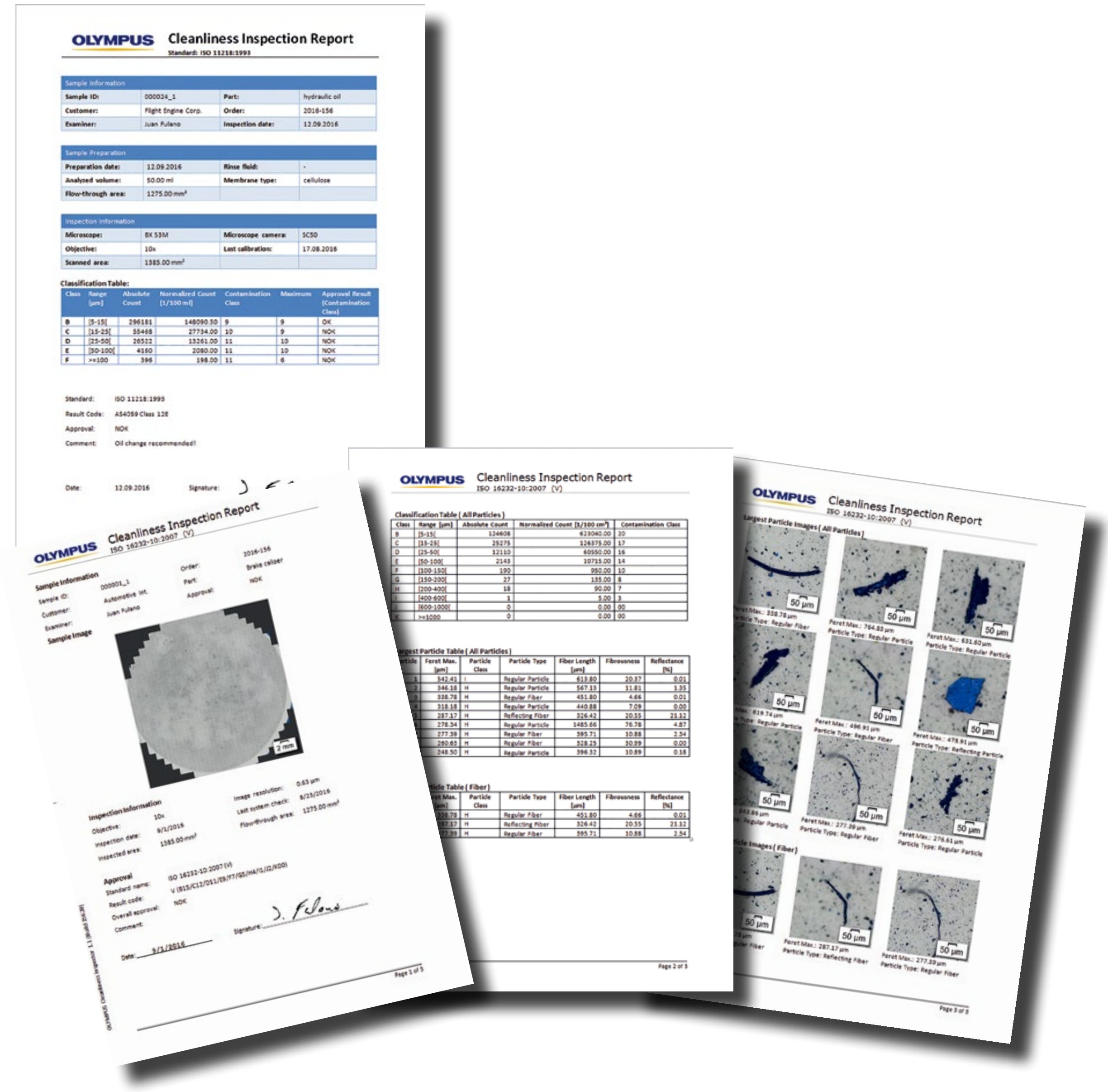
Inspection: Create Report

A report contains all of the measurement results and data for a filter membrane in a standardized form. Depending on the cleanliness standard used, it is mandatory to show specific results or measurement characteristics, such as the camera exposure time used or the scanned / examined area on the sample.

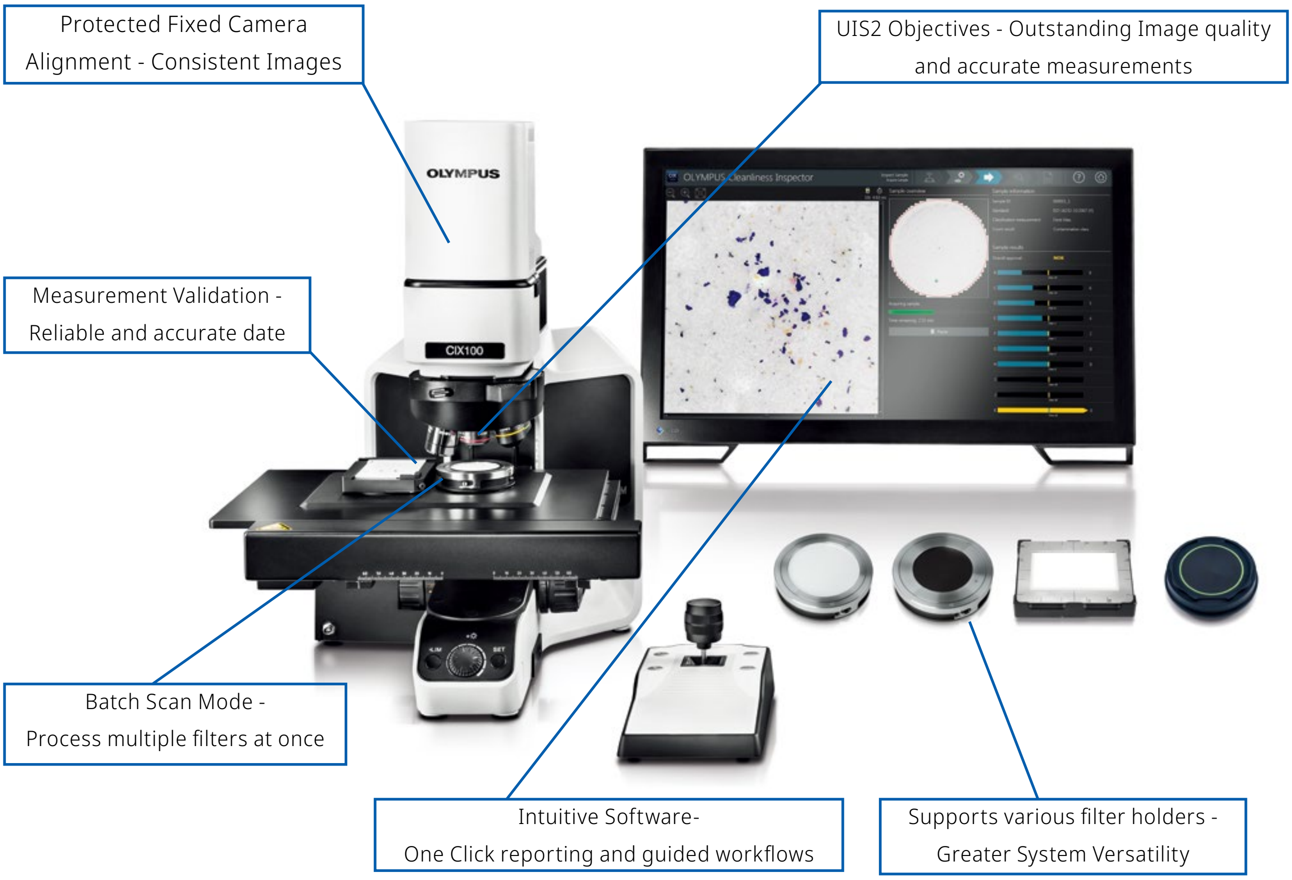
Some standards require the description of certain acquisition parameters, such as the name of the standard as well as the particle area coverage.

The appearance of the report can be adapted to the needs of the measurement and to the specifications of the company.

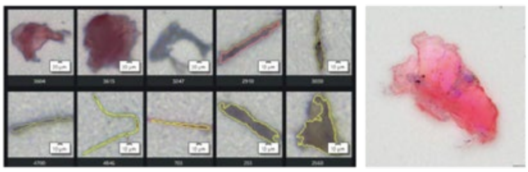
Classification tables and images of the largest particles can be shown. This all is defined in the templates of the report pages.



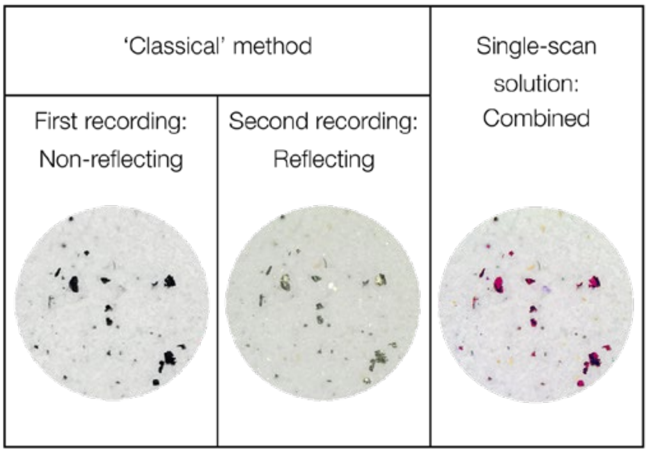
The Advantages of the CIX100 System



Quick and Powerful Sample Analysis



- Fast live analysis of particles and fibers
- Acquire height measurements and extended focus imaging for large particles
- Detect particles as small as 2.5 µm



- Distinguish reflective particles from non-reflective particles in one scan
- View the real color of particles using Real Color Slider

- **EVIDENT CORPORATION is ISO14001 certified.**
- **EVIDENT CORPORATION is ISO9001 certified.**

- Images on the PC monitors are simulated.
- Illumination devices for microscope have suggested lifetimes. Periodic inspections are required. Please visit our web site for details.
- Specifications and appearances are subject to change without any notice or obligation on the part of the manufacturer.

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